



LEAFLET: USER/PATIENT INFORMATION

ENANDROL 250 mg/ml solution for injection
Testosterone enanthate

Read this leaflet carefully and completely before you start using this medicine as 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 or nurse.
- This medicine has been prescribed only for you. You should not give it to other people. It may make them ill, even if they have the same signs of illness as you.
- If you experience any side effects, ask your doctor or pharmacist or nurse. This includes any possible side effects not mentioned in this leaflet. See section 4.

What you find in this leaflet:

1. What Enandrol is and what it is used for
2. What you need to know before using Enandrol
3. How to use Enandrol
4. Possible side effects
5. How to store Enandrol
6. Packaging contents and other information

1. What Enandrol is and what it is used for

Enandrol contains testosterone enanthate, a male hormone, as the active substance. Enandrol is injected into a muscle. Testosterone enanthate is a manufactured form of the male sex hormone, testosterone, which is naturally secreted. It is used in men to replace testosterone to treat different health problems caused by testosterone deficiency (male hypogonadism). This must be confirmed by two separate blood testosterone measurements and also include clinical symptoms such as: impotence, infertility, low sexual desire, fatigue, depressive states, bone loss caused by low testosterone hormone levels.

2. What you should know before using Enandrol

Do not use Enandrol

- if you are allergic to testosterone enanthate or any of the other ingredients of this medicine (see section 6);
- if you have had or have been suspected of having androgen-dependent prostate or mammary gland cancer;
- if you have had or have liver tumours;
- if you have had an increased level of calcium in your blood along with malignant tumours;
- if you have or have previously had a heart attack or other serious heart disease;
- if you have atherosclerosis (a condition in which blood fats are deposited on the vascular wall);
- if you suffer from diabetes;
- is contraindicated during pregnancy and breastfeeding.

Enandrol is not intended for use in children and adolescents. No data are available on the use of Enandrol in children and adolescents under 18 years of age. In children, in addition to causing early development of secondary male sexual characteristics (masculinisation), testosterone may cause accelerated bone growth and growth arrest, thereby altering final height. The appearance of acne vulgaris is to be expected.

Enandrol is not recommended for building muscle in healthy people or for increasing physical endurance.

Warnings and precautions

Tell your doctor if you have or have ever had:

- liver problems, including complaints of severe upper abdominal pain;
- suffer from sleep apnoea (interrupted breathing during sleep), as this can worsen;
- suffer from severe heart, liver or kidney disease; treatment with testosterone enanthate can cause severe complications in the form of water retention in the body, sometimes accompanied by (congestive) heart failure;
- high blood pressure or if you are being treated for high blood pressure, as testosterone can cause an increase in blood pressure;
- you have or have ever had blood clotting problems; thrombophilia (a blood clotting abnormality that increases the risk of thrombosis - blood clots in the blood vessels);
- have epilepsy, migraine, diabetes or a cancerous bone disease.

Like all oily solutions, Enandrol must be injected strictly intramuscularly and very slowly. In rare cases, pulmonary microembolism of oily solutions may cause symptoms such as coughing, dyspnoea, malaise, sweating, chest pain, dizziness or syncope. These reactions may occur during or immediately after injection and are reversible.

Testosterone enanthate should not be used in women as they may show signs of virilisation, e.g. acne, hair growth on the face or body and voice change.

Medical examination/consultation

Male hormones can contribute to the growth of prostate cancer and prostate glands (benign prostatic hypertrophy). Before your doctor injects testosterone enanthate, he or she will examine you to make sure you do not have prostate cancer. If you are older, you may have an increased risk of developing prostate enlargement when using testosterone enanthate. Although there is no clear evidence that sex hormones such as testosterone enanthate actually cause prostate cancer, they can increase the growth of any existing prostate cancers. As a precautionary measure, regular prostate examinations are recommended for men, especially if you are older.

If you are on long-term treatment, androgen treatment should be carried out regularly (see section 4. "Possible side effects").

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

- testosterone levels in the blood;
- general blood analysis.

Rare cases of benign (non-cancerous) and malignant (cancerous) liver tumours have been observed following the use of hormonal substances such as androgenic compounds. Although a tumour is unlikely to occur, they would present a health concern. In isolated cases, internal bleeding from these tumours could occur, which could be life-threatening.

Thus, you should seek medical advice when you suffer from severe abdominal pain. Not all unusual sensations you may feel in your upper abdomen can be considered as a possible sign of a tumour or bleeding. Pain that does not go away in a short time should however be better consulted with your doctor.

Children and adolescents

Enandrol is not intended for use in children and adolescents. No data are available on the use of Enandrol in children and adolescents under 18 years of age (see "*Do not use Enandrol*").

Elderly patients (over 65 years)

No dose adjustment is needed if you are over 65 (see "*Medical examination/consultation*").

Patients with liver disease

No studies have been conducted in patients with liver failure. The use of Enandrol is contraindicated in men with liver tumours or previous liver tumours (see "*Do not use Enandrol*").

Patients with kidney disease

No studies have been conducted in patients with renal impairment.

Enandrol is not recommended for building muscle in healthy people or for increasing physical strength. Enandrol may test positive in anti-doping tests.

Enandrol together with other medicines:

Tell your doctor or pharmacist if you have recently used any other medicines, including over-the-counter medicines. Your doctor may adjust your dose if you use any of the following:

- medicines used to treat nervousness and sleep problems (barbiturates or other enzyme inducers);
- medicines used to treat pain or inflammation (oxy-phenbutazone);
- blood-thinning tablets (anticoagulants);
- medicines for the treatment of diabetes, e.g. metformin.

If you are diabetic, your doctor may need to adjust your insulin dose.

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

Please make sure you have informed your doctor if you have an inherited or acquired blood clotting disorder, as it is important for your doctor to know before deciding to administer the intramuscular injection.

Pregnancy, breastfeeding and fertility

Testosterone enanthate is exclusively for men. It is not indicated for pregnant or breastfeeding women. Testosterone enanthate should not be used during pregnancy because of the possibility of virilisation (development of male sexual characteristics) of the female foetus.

Fertility

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

Driving vehicles and operating machinery

Enandrol does not affect the ability to drive vehicles and operate machinery.

3. How to use Enandrol

The injection will be given to you very slowly into a muscle by a doctor or nurse. The number of injections you are given per day or week is called your 'dose'. Depending on the condition you are being treated for, the doctor will administer the appropriate dose by injection into a muscle.

To stimulate the development of underdeveloped androgen-dependent organs and for the initial treatment of deficiency symptoms, 250 mg of testosterone enanthate is administered intramuscularly every 2-3 weeks.

For maintenance treatment: 250 mg testosterone enanthate intramuscularly every three to six weeks, depending on individual requirements.

The correct dose will be decided by your doctor. If you are not sure ask your doctor. Older male patients may be prescribed lower doses.

During treatment with Enandrol injection, your doctor will carry out regular checks on your prostate.

Enandrol is for intramuscular injection only. Special care must be taken to avoid injection into a blood vessel.

Enandrol solution for injection in vial form can be used several times after the first injection provided that the vial cap has not been removed and the remaining contents have remained hermetically sealed.

Starting treatment

Your doctor will measure your breast testosterone concentration before starting treatment and in the early stages of treatment.

Maintaining Enandrol levels during treatment

Your doctor will periodically measure your plasma testosterone concentration at the end of an interval between injections. If the level is too low, your doctor may decide to inject you more frequently. Plasma concentrations below the normal limit indicate the need to shorten the interval between injections. In case of increased plasma concentrations, your doctor may consider increasing the interval between injections. Do not miss injection appointments as your optimal testosterone level will not be maintained.

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

If you use more Enandrol than you should

Your doctor will determine the optimal injection interval to avoid excessive increases in blood testosterone concentrations. In case of accidental overdose, no special therapeutic measures are necessary, except stopping treatment or reducing the number of injections.

Symptoms of using more Enandrol include:

- irritability;
- nervousness;
- weight gain;
- long-lasting or frequent erections.

Tell your doctor if any of the above applies to you. Your doctor will inject you less often or stop treatment.

If you forget to use Enandrol

Please respect the injection intervals agreed with your doctor for optimal treatment efficacy.

If you stop using Enandrol

When Enandrol is stopped, testosterone deficiency symptoms may occur.

4. Possible side effects

Like all medicines, Enandrol can cause side effects, even if they don't occur in everyone. If any of the side effects become serious or any adverse reaction not mentioned in this leaflet occurs, inform your doctor or pharmacist.

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

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

- abnormally high red blood cell count;
- weight gain;
- buffets;
- acne;
- increased prostate-specific antigen (increase in a bi-oximal index in the blood);
- increased prostate size and associated problems;
- various reactions at the injection site (e.g. pain, discomfort, itching, redness, bruising or irritation);
- increased red blood cell count, haematocrit (the percentage of red blood cells in the blood) and haemoglobin (the oxygen-carrying component of red blood cells), detected by regular blood tests;
- increased erections.

Less common side effects (may affect up to 1 in 100 people)

- allergic reactions;
- increased appetite;
- changes in blood test results (e.g. increases in blood sugar and fat levels);
- depression, emotional disturbances, insomnia, nervousness, agitation, aggressiveness or irritability;
- headache, migraine or tremor, numbness of parts of the body;
- cardiovascular disease, increased blood pressure, hypertension or dizziness;
- bronchitis, sinusitis, coughing, shortness of breath, snoring, voice problems;
- diarrhea, nausea;
- abnormalities of liver function tests, e.g. increased aspartate aminotransferase;
- hair loss, skin reactions (e.g. redness, rash, papular rash (red spots appear), itching or dry skin);
- joint pain, pain in the hands and feet, muscle spasms, muscle pain or tightness, increased blood creatine phosphokinase values;
- reduced urine flow, urinary retention, need to urinate at night, urinary tract strains or pain when urinating;
- increased prostate cell count (prostatic intraepithelial neoplasia), hardening or swelling of prostate tissue, prostate disorders, increased sex drive, decreased interest in sex, testicular pain, hardening or enlargement of the breast tissue, breast pain, increased levels of the female hormone oestradiol in the blood, increased levels of testosterone in the blood, abnormal sperm production;
- fatigue, general weakness, hyperperspiration, night sweats.

Very rare adverse reactions (may affect <1/10000)

- benign or malignant tumours of the liver;
- liver enlargement;
- transient erythematous eruption, maculo-papular erythematous eruption;
- urinary tract disorders, nocturia;
- prostatic intraepithelial neoplasia (tumour).

The liquid and oily substance in Enandrol, if administered incorrectly (intravenously), can end up in the lungs (pulmonary microembolism of oily solutions) which, in rare cases, can lead to signs and symptoms such as coughing, dyspnoea, general malaise, excessive sweating, chest pain, dizziness, pricking or fainting. These reactions may occur during or immediately after injections and are reversible.

In addition to the side effects listed above, the following events have been reported after treatment with testosterone-containing preparations: nervousness, hostility, shortness of breath during sleep, various skin reactions including dandruff and oily skin, more frequent erections and very rare cases of yellowing of the skin and eyes (jaundice).

Treatment with preparations containing high doses of testosterone usually stops or reduces sperm production, although this usually returns to normal after stopping treatment. Testosterone replacement therapy for testicular disorders (hypogonadism) may, in rare cases, cause persistent painful erections (priapism). High doses or long-term administration of testosterone sometimes increase the incidence of fluid retention and oedema (swelling caused by fluid retention).

Reporting adverse reactions

If you experience any side effects, ask your doctor or pharmacist. This includes any possible side effects not mentioned in this leaflet. You can also report adverse reactions directly via the national reporting system, details of which are published on the website of the Medicines and Medical Devices Agency: www.amed.md or e-mail: farmacovigilenta@amed.md. By reporting adverse reactions, you can help provide additional information on the safety of this medicine.

5. How to store Enandrol

Keep out of sight and reach of children.

Store in a place protected from light and temperatures below 25 °C.

Do not use Enandrol after the expiry date written on the packaging after "EXP". The expiry date refers to the last day of that month.

No special storage conditions are required. Medicines should not be disposed of in household water or household waste. Ask your pharmacist how to dispose of medicines you no longer need. These measures will help protect the environment.

6. Package contents and other information

What Enandrol contains

The active substance is testosterone enanthate.

Each 1 ml solution for injection contains testosterone enanthate 250 mg.

Each 1 ml vial contains testosterone enanthate 250 mg.

Each 10 ml bottle contains testosterone enanthate 2500 mg. The other ingredients are: benzyl alcohol, benzylbenzoate, peach oil.

What Enandrol looks like and what it contains

Oily, clear, colourless or light yellow solution. Cardboard box of 2 x 1 ml ampoules of 2 x 5 ampoules in PVC containers. Cardboard box of 1 vial of 10 ml.

Registration certificate holder and manufacturer Registration certificate holder

SC Balkan Pharmaceuticals SRL,
N. Grădescu street, 4, MD-2002, or. Chisinau, Republic of Moldova

Manufacturer

SC Balkan Pharmaceuticals SRL,
7/A Industrial Street, MD-2091, or. Singera, Republic of Moldova

This leaflet was revised in April 2018

Detailed information on this medicine is available on the website of the Medicines and Medical Devices Agency (AMDM) <http://nomenclator.amed.md>.