

USER PACKAGE LEAFLET

Sustanon®

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

1. What Sustanon 250 is and what it is used for
2. Before Sustanon 250 is administered
3. How Sustanon 250 is administered
4. Possible side effects
5. Storing Sustanon 250

Sustanon 250, Solution for injection

- The active substance is:
Testosterone esters each milliliter of the oily solution contains:
- testosterone propionate 30 mg (milligrams)
- testosterone phenylpropionate 60 mg
- testosterone isocaproate 60 mg
- testosterone decanoate 100 mg
- The other ingredients are:
The solution for injection contains Arachis oil and benzyl alcohol.

1. WHAT SUSTANON 250 IS AND WHAT IT IS USED FOR

The active substances of Sustanon are turned into testosterone by your body.

Testosterone is the natural male hormone produced by the testicles, necessary for the normal growth, development and function of the male sex organs and for secondary male sex characteristics. It is necessary for the growth of body hair, the development of bones and muscles, and it stimulates the production of red blood cells. It also makes men's voice deepen. Preparations containing testosterone are used to replace testosterone in a person who has low or no natural testosterone (a condition known as hypogonadism).

Sustanon 250 solution for injection. A clear, pale yellow solution.

2. BEFORE SUSTANON 250 IS ADMINISTERED

Do not use Sustanon 250 IF:

- You have or have had a tumor of your prostate or breast
- You are allergic to one or more of the ingredients of the product
- You are under 3 years of age

Take special care with Sustanon 250

Extra supervision by a doctor is necessary, in the treatment of young boys since testosterone administration may cause early sexual development and disturb

growth. Extra supervision by a doctor is also necessary in elderly men, since male hormones may increase the size of the prostate gland. Additionally, at regular intervals, blood tests will be done to check the oxygen-carrying substance in your red blood cells (hemoglobin). In very rare cases the number of red blood cells will increase too much leading to complications. Medical checks may also be necessary in some other conditions. Therefore, tell your doctor if you have or have ever had:

- heart disease;
- kidney disease;
- liver disease;
- high blood pressure;
- prostatic complaints, such as problems with passing urine.

If you have sleep apnea (temporarily stopping breathing during your sleep), it may get worse if you are using testosterone-containing products. Let your doctor know if you are worried about this.

Using Sustanon 250 with food and drink

Not applicable.

Pregnancy

Ask your doctor or pharmacist for advice before taking any medicine. If you are pregnant, or think that you may be pregnant: do not use Sustanon 250.

Breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine. If you are breast-feeding: do not use Sustanon 250.

Driving and using machines

As far as is known Sustanon has no adverse effect on alertness and concentration.

Important information about some of the ingredients of Sustanon 250

Sustanon contains benzyl alcohol and should therefore not be given to children under 3 years of age.

Improper use

Misuse of androgens to enhance ability in sports carries serious health risks and is discouraged.

Using other medicines

Other medicines may influence the effects of Sustanon 250, or Sustanon 250 may affect other medicines. You must tell your doctor or pharmacist if you are using (or intend to use) anti-diabetic or anti-clotting medicines.

3. HOW SUSTANON 250 IS ADMINISTERED

This medicine should only be given by a doctor or a nurse. The injections are given deeply into a muscle (for instance in the buttock, upper leg or upper arm). Usually, the dosage is one injection of 1 ml per three weeks. If you have the impression that the effect of Sustanon 250 is too strong or too weak, talk to your doctor immediately.

If you use more Sustanon 250 than you should:

Not applicable.

If you forgot to take Sustanon 250:

Not applicable

Effects when treatment with Sustanon 250 is stopped:

The effects of Sustanon do

not stop immediately after discontinuation, but gradually subside.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Sustanon 250 can have side effects.

The side effects which are reported with testosterone therapy in general are:

- itching (pruritus);
- acne;
- nausea;
- changes in liver function tests;
- changes in cholesterol levels (changes in lipid metabolism);
- depression, nervousness, mood disturbances;
- muscle pain (myalgia);
- fluid retention in the tissues, usually marked by swelling of ankles or feet;
- high blood pressure (hypertension);
- increase in the number of red blood cells (cells which carry the oxygen in your blood);
- changes in sexual desire;
- prolonged abnormal, painful erection of the penis;
- disturbed formation of sperm;
- feminization (gynecomastia);
- prostatic growth to a size representative for the concerned age group;
- increased levels of a blood marker which is associated with prostate cancer (PSA increased);
- increased growth of a small prostate cancer which had not been detected yet (progression of a sub-clinical prostatic cancer).

Due to the nature of Sustanon 250, side effects cannot be quickly reversed by discontinuing medication. Injectables in general, may cause local reaction at the injection site. If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. STORING SUSTANON 250

Store between 8 °C and 30 °C, Protected from light
Do not use Sustanon 250 after the expiry date stated on the carton or label.

Keep Sustanon 250 out of reach and sight of children.

If you have any further questions or require the full prescribing information for Sustanon 250 please consult your doctor or pharmacist.

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This leaflet was revised on June 2006

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament. The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers
& Union of Arab Pharmacists