

Package Leaflet: Information for the patient

Sustanon 250, 250 mg/ml, solution for injection (testosterone esters)

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 further questions, please ask your doctor or your 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 Sustanon 250 is and what it is used for
2. What you need to know before Sustanon 250 is administered
3. How Sustanon 250 is administered
4. Possible side effects
5. How to store Sustanon 250
6. Contents of the pack and other Information

1. What Sustanon 250 is and what it is used for

Sustanon 250 is a clear pale yellow solution for injection containing the active ingredient testosterone in 4 (250 mg/ml) separate forms. The active substances of Sustanon 250 (see section 6 “What Sustanon 250 contains”) are turned into testosterone by your body. Testosterone is a natural male hormone known as an androgen.

In men, testosterone is produced by the testicles. It is 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 voices deepen.

Sustanon 250 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 and bone loss caused by low hormone levels.

Sustanon 250 may also be used as supportive therapy for female-to-male transsexuals.

2. What you need to know before Sustanon 250 is administered

Do not take Sustanon 250:

- If you are pregnant or think you may be pregnant (see “Pregnancy, breast-feeding and fertility”).
- If you have or have had a tumour of your prostate or breast, or are suspected to have one of these tumours.
- In children under the age of 3 years.
- If you are allergic to testosterone or to any of the other ingredients of this medicine (listed in section 6)

- If you are allergic to peanuts or soya (see Section 2 "Important information about some of the ingredients of Sustanon 250").

Warnings and precautions

If you notice any signs of masculinisation (for instance lowering of the voice or increase in body or facial hair), consult your doctor immediately.

Treatment with male hormones like testosterone may increase the size of the prostate gland, especially in elderly men. Therefore your doctor will examine your prostate gland at regular intervals by digital rectal examination (DRE) and blood tests for prostate-specific antigen (PSA).

Additionally, at regular intervals, blood tests will be done to check the oxygen-carrying substance in your red blood cells (haemoglobin). In very rare cases the number of red blood cells will increase too much leading to complications.

The following blood checks should be carried out by your doctor before and during the treatment: testosterone blood level, full blood count.

Medical checks may also be necessary in some other conditions.

Talk to your doctor or pharmacist before you start using this medicine if you ever had, still have or are suspected to have:

- Breast cancer which has spread to the bones;
- Kidney or lung cancer;
- Heart disease;
- Kidney disease;
- Liver disease;
- High blood pressure;
- Diabetes mellitus;
- Epilepsy;
- Migraine, headaches;
- Prostatic complaints, such as problems with passing urine;
- 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.

If you are suffering from severe heart, liver or kidney disease, treatment with Sustanon 250 may cause severe complications in the form of water retention in your body sometimes accompanied by (congestive) heart failure.

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

If you have sleep apnoea (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. Extra supervision by your doctor may be necessary in case you are overweight or suffer from chronic lung disease.

During treatment you should also tell your doctor:

- if you are a female-to-male transsexual. You should have special assessments, including psychiatric assessment, before treatment is started.
- if you are a **female-to-male transsexual** and have a personal or family history of breast cancer and a personal history of endometrial cancer.

Children and adolescents

The safety and efficacy of this medicine has not been adequately determined in children and adolescents. Extra supervision by your doctor is necessary in the treatment of children and adolescents since testosterone administration in general may cause early sexual development and limits growth (see section 4 “Children and adolescents”).

Blood tests may be affected.

For **female-to-male transsexuals**, Sustanon 250 may be given as part of a programme of treatment, including surgery.

Other medicines and Sustanon 250

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines – even those not prescribed.

Other medicines may influence the effects of Sustanon 250, or Sustanon 250 may affect other medicines. Therefore, you must tell your doctor or pharmacist if you are using, or are about to use:

- medicines used to treat diabetes. It may be necessary to adjust the dose of your blood sugar reducing medicine. Like other androgens, testosterone may increase the effect of insulin. 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.
- Medicines to reduce the clotting of your blood (anti-coagulants);
- Certain medicines that change the amount of enzymes to be made in the liver e.g. medicines used to treat epilepsy (phenobarbital).

These drugs may affect the levels of testosterone in your body and your doctor may need to adjust the dose or frequency of your Sustanon 250.

The use of androgens like Sustanon 250 may lead to a reduction of the doses of these medicines.

Tell your doctor or pharmacist if you are using or about to use the hormone ACTH or corticosteroids (used to treat various conditions such as rheumatism, arthritis, allergic conditions and asthma). The use of androgens like Sustanon 250 may increase the risk of water retention especially if your heart and liver are not working properly.

Androgens may also affect the results of some laboratory tests (e.g. thyroid gland). Therefore, you must tell your doctor or the laboratory staff performing the tests that you are using this medicine.

Sustanon 250 with food and drink

This medicine can be injected without taking consideration of meals and drinks.

Pregnancy, breast-feeding and fertility

Sustanon 250 must not be taken by women who are pregnant or think they are pregnant (see section 2 “Do not use Sustanon 250”), or by women who are breast-feeding.

In men, treatment with Sustanon 250 can lead to fertility disorders by repressing sperm formation.

In women, treatment with this medicine can lead to an irregular or absent menstrual cycle.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

As far as is known this medicine has no influence on driving and using machines.

Sustanon 250 contains Arachis oil (peanut oil) (refined) and Benzyl alcohol (E 1519)

This medicine also contains:

- **Arachis oil (peanut oil) (refined)** - If you are allergic to peanut or soya, do not use this medicinal product (see “Do not use Sustanon 250”).
- **Benzyl alcohol (E 1519)** (100 mg per ml of solution) - Products containing benzyl alcohol must not be given to premature babies or neonates. Benzyl alcohol may cause toxic reactions and allergic reactions in infants and children up to 3 years old.

Improper use

If you are a patient who participates in competitions governed by the World Anti-Doping Agency (WADA), then you should consult the WADA-code before using this medicine as Sustanon 250 can interfere with anti-doping testing.

The misuse of this medicine to enhance ability in sports carries serious health risks and is discouraged.

Drug abuse and dependence

This medicine should only be given by a doctor or nurse and used exactly as your doctor has told you. Abuse of testosterone, especially if you use 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 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.

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). The dose depends on your illness and how bad it is. Your doctor will decide the dose.

Usually, the dosage is one injection of 1 ml every three weeks.

If you have the impression that the effect of this medicine is too strong or too weak, talk to your doctor or nurse immediately.

Use in children and adolescents

The safety and efficacy of this medicine have not been adequately determined in children and adolescents. Pre-pubertal children using this medicine will be monitored by your doctor (see section 2 “Take special care with Sustanon 250”).

If you use more Sustanon 250 than you should

Your doctor or nurse will inject this medicine into you. If you have the impression that the effect of this medicine is too strong then please talk to your doctor or nurse immediately.

The following effects may happen:

- Frequent erections in men;
- Changes in your red blood cells (polycythaemia), which your doctor may monitor you for.

If you forgot to get your injection of Sustanon 250

Your doctor or nurse will inject this medicine into you. Should you miss a scheduled injection then please talk to your doctor or nurse as soon as possible. No double dose should be injected to make up for forgotten individual doses.

If you stop treatment with Sustanon 250

The effects of this medicine do not stop immediately after discontinuation, but gradually subside.

When treatment with this medicine is stopped, complaints such as those experienced before treatment may re-occur within a few weeks.

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

Adults (female-to-male transsexuals)

Sustanon 250:

Doses vary from one injection of 1 ml every two weeks to one injection of 1 ml every four weeks.

4. Possible side effects

Like all medicines, this medicine can cause side effects although not everybody gets them. In general, the side effects which are reported with testosterone therapy include:

Common (may affect up to 1 in 10 people)

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

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

The oily liquid Sustanon 250 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 oily microembolism.

Not known (cannot be estimated from available data)

- Itching (pruritus);
- Acne;
- Nausea;
- Changes in liver function tests;
- Changes in cholesterol levels (changes in lipid metabolism);
- Depression, nervousness, mood alterations;
- Muscle pain (myalgia);

- Fluid retention in the tissues, usually marked by swelling of ankles or feet;
- High blood pressure (hypertension);
- Changes in sexual desire;
- Prolonged abnormal, painful erection of the penis;
- Ejaculation disorder;
- Disturbed formation of sperm;
- Feminisation (gynaecomastia);
- 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 has 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.

Side effects in women:

In women, this product may induce signs of masculinisation (for example, lowering of the voice, and increase in body or facial hair.)

Children and adolescents:

The following side effects have been reported in pre-pubertal children using androgens:

- Early sexual development;
- Penis enlargement;
- An increased frequency of erections;
- Growth limitation (limited body height)

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 Yellow Card Scheme 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 Sustanon 250

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

Do not use this medicine after the expiry date stated on the carton or label after the term “exp” (expiry date). The expiry date refers to the last day of that month.

Store below 30°C. Do not refrigerate or freeze.
Store in the original package in order to protect from light.

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 to protect the environment.

6. Contents of the pack and other information

What Sustanon 250 contains

The active substance is:

Each milliliter of the oily solution contains the following

- testosterone propionate, 30 mg
- testosterone phenylpropionate, 60 mg
- testosterone isocaproate, 60 mg
- testosterone decanoate, 100 mg

All four compounds are esters of the natural hormone testosterone. The total amount of testosterone per ml is 176 mg.

The other ingredients are:

The solution for injection contains Arachis oil (refined) and Benzyl Alcohol (E 1519).

What Sustanon 250 looks like and contents of the pack

Sustanon 250 is a clear, pale yellow solution for deep intramuscular injection.

Each colourless glass ampoule is filled with 1 ml of Sustanon 250.

A box of Sustanon 250 contains 1 ampoule.

Not all pack sizes are marketed.

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

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