

SUSTANON 250 solution for injection

Testosterone propionate, phenylpropionate, isocaproate and decanoate

What is in this leaflet

This leaflet answers some common questions about SUSTANON 250. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using SUSTANON 250 against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What SUSTANON 250 is used for

The active substances of SUSTANON 250 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. 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 is also used in men for the treatment of osteoporosis caused by androgen deficiency.

SUSTANON 250 is used in female to male transsexuals for development of male sexual characteristics.

Ask your doctor if you have any questions about why SUSTANON 250 has been prescribed for you.

Your doctor may have prescribed SUSTANON 250 for another reason.

This medicine is available only with a doctor's prescription.

Before you use SUSTANON 250

When you must not use it

Do not use SUSTANON 250 if:

- you are pregnant or think you may be pregnant or by women who are breastfeeding.
- 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. 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.
- you are allergic to one or more of the ingredients of this medicine listed under PRODUCT DESCRIPTION-Ingredients
- you are allergic to peanuts or soya.

If you are not sure whether you should start using SUSTANON 250, talk to your doctor.

Before you start to use it

Tell your doctor if you have or have ever had, still have or are suspected to have any of the following medical conditions:

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

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.

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. Medical checks may also be necessary in some other conditions.

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.

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.

SUSTANON 250 must not be taken by women who are pregnant or think that they are pregnant or by women who are breast feeding.

In women, treatment with this medicine can lead to an irregular or absent menstrual cycle. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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

If you have not told your doctor about any of the above, tell them before you start using SUSTANON 250.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

You should also tell any health professional who is prescribing a new medication for you that you are taking SUSTANON 250.

Other medicines may influence the effects of SUSTANON 250 or SUSTANON 250 may affect other medicines. These include:

- anti-coagulants or medicines used to reduce or prevent blood clots.
- anti-diabetic medicines such as insulin used to control blood sugar levels and to treat diabetes. 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.
- 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 or 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 laboratory staff performing the tests that you are using this medicine.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking SUSTANON 250.

How to use SUSTANON 250

This medicine should only be given by a doctor or a nurse.

The injections are given deeply into a muscle (e.g. the buttock, upper leg or upper arm). The content of each vial or ampoule are for one injection only.

How much to take

Standard treatment is usually one injection of 1 mL per three weeks.

Dosage should be adjusted by your doctor in response to individual requirements.

When to take it

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

If you forget to take it

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 the forgotten individual doses.

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.

While you are using SUSTANON 250

Things you must do

Keep all your appointments so that your progress can be checked.

Your doctor may do some blood tests at regular intervals to make sure the medicine is working and to prevent unwanted side effects.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking SUSTANON 250.

Things you must not do

Do not give SUSTANON 250 to anyone else, even if they have the same condition as you.

It may harm them, even if their signs of illness are the same as yours.

Do not use this product if it has passed the expiry date printed on the pack, or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Things to be careful of

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

In case of overdose

If you take too much (overdose)

These injections are given under medical supervision, and it is very unlikely that you will be given too much. If several doses are given at once it is not a medical emergency.

However, you should consult your doctor if you have the impression that the effect of this medicine is too strong as side-effects are dependent on dosage, dose interval and your individual sensitivity.

Do this even if there are no signs of discomfort or poisoning.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using SUSTANON 250.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

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

- pain at the injection site;
- itching;
- acne;
- nausea;
- changes in liver function tests;
- changes in cholesterol levels (changes in lipid metabolism);
- depression, nervousness, mood disturbances;
- muscle pain;
- fluid retention e.g. swelling of ankles and feet;
- increase in weight;
- high blood pressure;
- increase in the number of red blood cells;
- changes in sexual desire;

- prolonged abnormal, painful erection of the penis;
- disturbed formation of sperm;
- breast enlargement in men;
- 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 to a sub-clinical prostatic cancer.)

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

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

- early sexual developments;
- penis enlargement;
- an increased frequency of erections;
- growth limitation (limited body heights).

Some side effects have no symptoms. These side effects e.g. changes in cholesterol levels, changes in liver function tests, increase in the number of red blood cells or increased blood pressure can only be found when your doctor does tests to check your progress.

Due to the nature of SUSTANON 250, side effects cannot be quickly reversed by discontinuing medication.

Rare side effects:

The oily liquid in 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.

Tell your doctor if you notice any other side effects.

Other side effects not listed above may also occur in some patients.

After using SUSTANON 250

Storage

Keep SUSTANON 250 in the original box in a safe place out of reach of children.

Keep it in a cool dark place where the temperature stays below 30°C. Do not refrigerate or freeze as this makes the product difficult to inject.

Do not use SUSTANON 250 after the expiry date stated on the label after the term

'exp'.

Disposal

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.

Product description

What it looks like

Each pack contains a 1 clear glass ampoule of an oily, pale yellow, clear liquid.

Each glass ampoule is filled with 1 mL of SUSTANON 250.

Do not use this medicine if the glass ampoule is broken or damaged or if the product doesn't look right.

Ingredients

Active ingredients:

SUSTANON 250 contains several testosterone esters as the active ingredients.

Each 1 mL ampoule of SUSTANON 250 contains:

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

Inactive ingredients:

- arachis (peanut) oil – base
- benzyl alcohol – preservative.

Sponsor details

SUSTANON 250 solution for injection is supplied in New Zealand by:

Pharmacy Retailing (NZ) Ltd
Trading as Healthcare Logistics
Auckland, New Zealand

Date of preparation

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