

Sustanon '250'

Testosterone propionate, phenylpropionate, isocaproate and decanoate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Sustanon. 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 against the benefits they expect it will have for you.

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

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.

What Sustanon is used for

Sustanon is used to treat confirmed testosterone deficiency in males.

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

Testosterone is the natural male hormone known as an androgen. In men, testosterone produced by the testicles. It is necessary for the 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).

Your doctor may have prescribed it for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed to you.

A doctor's prescription is required to obtain this medicine.

This medicine is not expected to affect your ability to drive a car or operate machinery.

Before you use Sustanon

When you must not use it

Do not use Sustanon if

- If you have or have had a tumour of your prostate or breast or are suspected to have one of these tumors.
- In children under the age of 3 years.
- you have high levels of calcium in the blood (hypercalcaemia) or high levels of calcium in the urine (hypercalciuria)
- If you are allergic to one or more of the ingredients of the product.
- you are allergic to peanuts or soya.

Sustanon is for use by boys or men only.

Do not give Sustanon to women, especially if pregnant or breast-feeding.

It may give increased male characteristics to an unborn baby.

There is not enough data available for the safe use of Sustanon during lactation.

Before you start to use it

Tell your doctor or pharmacist if you 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).

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.

Sustanon should not be given to children under 3 years of age.

This is because Sustanon contains benzyl alcohol, which may cause toxic or 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 can interfere with anti-doping testing.

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

Taking other medicines

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

pharmacy, supermarket or health food shop.

Some medicines and Sustanon may interfere with each other. These include:

- anticoagulants or medicines used to prevent blood clots
- anti-diabetic medicines such as insulin used to treat diabetes and/or other medicines to control blood sugar levels.

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

These medicines may influence the effects of Sustanon or Sustanon may affect other medication. You may need different amounts of your medicines, or you may need to take different medicines.

Also 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 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.

Using Sustanon with food and drink

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

Pregnancy, breast-feeding and fertility

Sustanon is not for use in women, therefore this medicine must not be taken by women who are pregnant or think that they are pregnant, or by women who are breast-feeding.

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

If you 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.

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.

How Sustanon is given

How the injections are given

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 contents of each vial or ampoule are for one injection only.

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

How much to take

Standard treatment is usually one injection of Sustanon '250' every 3 weeks.

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

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

If you are given 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 as side-effects are dependent on dosage, dose interval and your individual sensitivity.

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.

If you forgot to get your injection of Sustanon

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.

While you are using Sustanon

Keep all of 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.

As far as known, Sustanon has no adverse effects on alertness and concentration.

Side Effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Sustanon.

In general the side effects which are reported with testosterone therapy include:

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

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)

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.

Tell your doctor if you notice any other side effects.

Other side effects not listed in this leaflet also occur in some people.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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

After Using Sustanon

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.

Storage

Keep Sustanon in the original box in a safe place out of reach and sight of children.

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

Do not use Sustanon after the expiry date stated on the label after the term 'exp'.

Disposal

Return any unused medicine to your pharmacist.

Product Description

What it looks like

Each pack contains a clear glass ampoule or vial.

Sustanon is a clear pale yellow solution for injection containing the active ingredient testosterone in 4 (250 mg/ml) separate forms.

Do not use this medicine if the glass ampoules or vials are broken or damaged or if the product doesn't look right.

Ingredients

Sustanon contains several testosterone esters as the active ingredients.

Each 1 mL of Sustanon '250' contains:

- 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.

It also contains:

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

Supplier

This medicine is supplied in Australia by:
Aspen Pharmacare
34-36 Chandos St
St Leonards
NSW 2065

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Australian Registration Numbers:

- Sustanon '250' injection ampoule (AUST R 14521)
- Sustanon '250' injection vial (AUST R 190717)