

# SUSTANON '250' injection

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I being given SUSTANON?

SUSTANON contains four testosterone esters as the active ingredients which are turned into testosterone by your body. SUSTANON is used to treat confirmed testosterone deficiency in males.

For more information, see Section [1. Why am I being given SUSTANON?](#) in the full CMI.

### 2. What should I know before I receive SUSTANON?

Do not use if you have ever had an allergic reaction to any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are planning to father a child.**

For more information, see Section [2. What should I know before I receive SUSTANON?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with SUSTANON and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How is SUSTANON given?

- The usual dose is one injection of SUSTANON '250' every 3 weeks. Your doctor may adjust this dose based on your needs.
- The injections are given deeply into a muscle (e.g. the buttock, upper leg or upper arm), by a doctor or nurse only.

More instructions can be found in Section [4. How is SUSTANON given?](#) in the full CMI.

### 5. What should I know while using SUSTANON?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using SUSTANON</li><li>• If you have the impression that the effect of this medicine is too strong or too weak, talk to your doctor or nurse immediately.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• As far as is known this medicine has no influence on driving and using machines.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep SUSTANON in the original box in a safe place out of reach and sight of children.</li><li>• Keep it in a cool dark place where the temperature stays between below 30°C.</li><li>• Do not refrigerate as this makes the product difficult to inject.</li></ul>

For more information, see Section [5. What should I know while using SUSTANON?](#) in the full CMI.

### 6. Are there any side effects?

Less serious side effects of SUSTANON include pain at injection site, itching, acne, nausea, muscle pain, increased weight, high blood pressure, increased or decreased libido, disturbed sperm formation, breast enlargement in men, prostate enlargement, fluid retention, a size reduction of testes, hair loss, and various changes in blood test results. Less serious side effects found in children also include early sexual development, penis enlargement, an increased frequency of erections, and growth limitation (limited body height).

Serious side effects of SUSTANON include mood changes; signs of an allergic reaction; yellowing of the skin and eyes (jaundice); prolonged abnormal, painful erection of the penis; growth of undetected prostate cancer; coughing, increased sweating, chest pain, and feeling faint; and pain, swelling, redness, and enlarged veins in the affected area.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# SUSTANON '250' injection

**Active ingredients:** *testosterone propionate, testosterone phenylpropionate, testosterone isocaproate and testosterone decanoate.*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using SUSTANON '250' (or SUSTANON).

**You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using SUSTANON.**

**Where to find information in this leaflet:**

- [1. Why am I being given SUSTANON?](#)
- [2. What should I know before I receive SUSTANON?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is SUSTANON given?](#)
- [5. What should I know while using SUSTANON?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I being given SUSTANON?

SUSTANON is used to treat confirmed testosterone deficiency in males.

SUSTANON contains four testosterone esters as the active ingredients which are turned into testosterone by your body. Testosterone is the natural male hormone known as an androgen. In men, testosterone is 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).

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

Your doctor may have prescribed it for another reason.

## 2. What should I know before I receive SUSTANON?

### Warnings

**You should not be given SUSTANON if:**

- you are allergic to peanuts, soya or any of the ingredients listed at the end of this leaflet.
  - Some symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue, or any

other parts of the body; rash, itching or hives on the skin

- you have any of the following medical conditions:
  - a current or past prostate or breast tumour or are suspected to have one of these tumours
  - high levels of calcium in the blood (hypercalcaemia)
  - high levels of calcium in the urine (hypercalciuria).
- you are a woman
- in children under the age of 3 years
- it has passed the expiry date printed on the pack
- the packaging is torn or shows signs of tampering.

### Check with your doctor if you:

- have had any allergy to any other medicines, or any other substances, such as foods, preservatives, or dyes.
- have any other medical conditions, especially the following:
  - 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). 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).
  - sleep apnoea (temporarily stopping breathing during your sleep).

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Fertility, pregnancy and breastfeeding

**If you are planning to have a baby, ask your doctor for advice before taking this medicine.**

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

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. It may give increased male characteristics to an unborn baby.

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

### Use in 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 limit growth.

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

SUSTANON contains benzyl alcohol which may cause toxic or allergic reactions in infants and children up to 3 years old.

### Improper use

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

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.

## 3. What if I am taking other medicines?

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

Some medicines may interfere with SUSTANON and affect how it works. 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. 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
- adrenocorticotrophic hormone (ACTH)
- corticosteroids (used to treat various conditions such as rheumatism, arthritis, allergic conditions and asthma).

### Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect SUSTANON.

## 4. How is SUSTANON given?

### How much is given

Standard treatment is usually one injection of SUSTANON every 3 weeks. The dosage will be adjusted by your doctor in response to your individual requirements.

Pre-pubertal children using this medicine will be monitored by your doctor.

### How it is 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 ampoule are for one injection only.

### Using SUSTANON with food and drink

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

### If you forget to get your injection of SUSTANON If you miss a scheduled injection, then 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 are given too much SUSTANON

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.

## 5. What should I know while using SUSTANON?

### Things you should do

#### Remind any doctor, dentist, or pharmacist you visit that you are using SUSTANON.

SUSTANON may 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.

#### 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.

#### Talk to your doctor or nurse immediately if you have the impression that the effect of this medicine is too strong or too weak.

### 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.

**Ask your doctor or pharmacist if you have any further questions on the use of this medicine.**

### Driving or using machines

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

### Looking after your medicine

**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.**

### Getting rid of any unwanted medicine

Return any unused medicine to your pharmacist.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• pain at the injection site</li> <li>• itching</li> <li>• acne</li> <li>• nausea</li> <li>• muscle pain</li> <li>• increased weight</li> <li>• high blood pressure</li> <li>• increase in the number of red blood cells</li> <li>• increased or decreased sexual desire</li> <li>• disturbed formation of sperm</li> <li>• breast enlargement in men</li> <li>• prostate enlargement</li> <li>• fluid retention e.g. swelling of ankles and feet and weight gain</li> <li>• reduction in size of testes</li> <li>• hair loss.</li> </ul> <p><b>Some side effects have no symptoms and are seen only in blood tests:</b></p> <ul style="list-style-type: none"> <li>• changes in liver function tests</li> <li>• changes in cholesterol levels (changes in lipid metabolism)</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<ul style="list-style-type: none"> <li>• increased levels of a blood marker which is associated with prostate cancer (PSA increased)</li> <li>• increase in the number of red blood cells</li> <li>• increase blood pressure.</li> </ul> <p><b>In children and adolescents:</b></p> <ul style="list-style-type: none"> <li>• early sexual development</li> <li>• penis enlargement</li> <li>• an increased frequency of erections</li> <li>• growth limitation (limited body height).</li> </ul>	
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### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• depression, nervousness, mood alterations</li> <li>• signs of allergy such as rash, swelling of the face, lips, mouth, throat or other parts of the body, shortness of breath, wheezing or trouble breathing</li> <li>• yellowing of the skin and eyes, also called jaundice</li> <li>• prolonged abnormal, painful erection of the penis</li> <li>• growth of undetected prostate cancer</li> <li>• coughing, increased sweating, chest pain, feeling faint</li> <li>• pain, swelling, redness, and enlarged veins in the affected area.</li> </ul>	<p><b>Call your doctor immediately or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>
<p><b>During and immediately after each injection:</b></p> <ul style="list-style-type: none"> <li>• cough</li> <li>• shortness of breath</li> <li>• feeling generally unwell</li> <li>• excessive sweating</li> <li>• chest pain</li> <li>• dizziness</li> <li>• pins and needles</li> <li>• fainting.</li> </ul> <p>The patient should therefore be observed in order to allow for early recognition of possible signs and symptoms of pulmonary oil microembolism.</p>	<p><b>These rare reactions may occur during or immediately after the injection and are reversible.</b></p>

SUSTANON is also associated with an increased risk of prostate cancer.

**Tell your doctor, nurse or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor, nurse or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

### What SUSTANON contains

<b>Active ingredients (main ingredients)</b>	Contains a total testosterone content of 176 mg/mL in four separate compound forms: <ul style="list-style-type: none"><li>• testosterone propionate 30 mg</li><li>• testosterone phenylpropionate 60 mg</li><li>• testosterone isocaproate 60 mg</li><li>• testosterone decanoate 100 mg.</li></ul>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• arachis (peanut) oil (base)</li><li>• benzyl alcohol (preservative).</li></ul>
<b>Potential allergens</b>	<ul style="list-style-type: none"><li>• peanut oil.</li></ul>

**Do not take this medicine if you are allergic to any of these ingredients.**

### What SUSTANON looks like

SUSTANON is a clear, colourless glass ampoule containing 1 mL of pale-yellow oily solution.

Pack size of 1 ampoule.

Australian Registration number: AUST R 14521

### Who distributes SUSTANON

Aspen Pharmacare Australia Pty Ltd  
34-36 Chandos St  
St Leonards NSW 2065  
Australia

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