NEW ZEALAND DATA SHEET

1. PRODUCT NAME

SUSTANON 250 (250 mg testosterone esters solution for injection)

Presentations that are not currently available

The vials are currently not available.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Name and strength of the active substances -

testosterone proprionate	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 1 mL is 176 mg.

List of excipients -

1 mL arachis oil and the solution also contains 10 per cent benzyl alcohol.

For the full list of excipients, see Section 6.1 List of excipients.

3. PHARMACEUTICAL FORM

Oily solution for intramuscular use. A clear, pale yellow solution. Each clear glass ampoule or vial contains 1 mL in arachis oil.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Testosterone replacement therapy in males for conditions associated with primary and secondary hypogonadism, either congenital or acquired.

In female to male transsexuals:

- masculinization

Moreover, in men testosterone therapy may be indicated in osteoporosis caused by androgen deficiency.

4.2 Dose and method of administration

In general, the dose should be adjusted according to the response of the individual patient.

Dose

Adults (incl. elderly):

Usually, one injection of 1 ml per three weeks is adequate.

Paediatric population:

Safety and efficacy in children and adolescents, have not yet been established. Pre-pubertal children treated with SUSTANON should be treated with caution (see Section **4.4 Special Warnings and Precautions for use**).

SUSTANON contains benzyl alcohol and is contraindicated in children under 3 years of age.

Method of administration
SUSTANON should be administered by deep intramuscular injection.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1, including arachis oil. SUSTANON is therefore contraindicated in patients allergic to peanuts or soya (see Section **4.4 Special Warnings and Precautions for use**)
- Pregnancy
- Known or suspected carcinoma of prostate or breast cancer
- Breastfeeding.

4.4 Special Warnings and Precautions for use
Medical Examination:
Testosterone level should be monitored at baseline and at regular intervals during treatment. Clinicians should adjust the dosage individually to ensure maintenance of eugonadal testosterone levels.

Physicians should consider monitoring patients receiving SUSTANON before the start of treatment, at quarterly intervals for the first 12 months and yearly thereafter for the following parameters:

- digital rectal examination (DRE) of the prostate and PSA to exclude benign prostate hyperplasia or a sub-clinical prostate cancer (see Section **4.3 Contraindications**)
- hematocrit and haemoglobin to exclude polycythemia.

Conditions that need supervision:
Patients, especially the elderly, with the following conditions should be monitored for:

- **Tumours – Mammary carcinoma, hypernephroma, bronchial carcinoma and skeletal metastases.** In these patients hypercalcemia may develop spontaneously, also during androgen therapy. The latter can be indicative of a positive tumour response to the hormonal treatment. Nevertheless, the hypercalcemia should first be treated appropriately and after restoration of normal calcium levels, hormone therapy can be resumed.

- **Pre-existing conditions –** In patients with pre-existing cardiac, renal or hepatic

insufficiency/disease androgen treatment may cause complications characterized by edema with or without congestive heart failure. In such cases treatment must be stopped immediately. Patients who experienced myocardial infarction, cardiac-, hepatic- or renal insufficiency, hypertension, epilepsy, or migraine should be monitored due to the risk of deterioration of or reoccurrence of disease. In such cases treatment must be stopped immediately. There is insufficient long-term safety data to assess a potentially increased risk of cardiovascular disease.

- **Diabetes mellitus –** Androgens in general and SUSTANON can improve glucose tolerance in diabetic patients (see Section 4.5 Interactions with other medicines and other forms of interaction).
- **Clotting disorders –** Testosterone should be used with caution in patients with thrombophilia or risk factors for venous thromboembolism (VTE), as there have been post-marketing studies and reports of thrombotic events (e.g. deep vein thrombosis, pulmonary embolism, ocular thrombosis) in these patients during testosterone therapy. In thrombophilic patients, VTE cases have been reported even under anticoagulation treatment, therefore continuing testosterone treatment after first thrombotic event should be carefully evaluated. In case of treatment continuation, further measures should be taken to minimise the individual VTE risk.
- **Anti-coagulant therapy –** Androgens in general and SUSTANON can enhance the anti- coagulant action of coumarin-type agents (see Section 4.5 Interactions with other medicines and other forms of interaction).
- **Sleep apnea –** There is insufficient evidence for a recommendation regarding the safety of treatment with testosterone esters in men with sleep apnea. Good clinical judgment and caution should be employed in patients with risk factors such as adiposity or chronic lung diseases

- **Pulmonary oil microembolism -** As with all oily solutions, SUSTANON must be injected strictly intramuscularly and very slowly. Pulmonary microembolism of oily solutions can in rare cases lead to signs and symptoms such as cough, dyspnoea, malaise, hyperhydrosis, chest pain, dizziness, paraesthesia, or syncope. 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. Treatment is usually supportive e.g. by administration of supplemental oxygen.

Effects on laboratory tests:

Androgens may decrease levels of thyroxine-binding globulin resulting in decreased total T4 serum levels and increased resin uptake of T3 and T4. Free thyroid hormone levels remain unchanged, however, and there is no clinical evidence of thyroid dysfunction.

Adverse events:

If androgen-associated adverse reactions occur (see Section 4.8 Undesirable effects), treatment with SUSTANON should be discontinued and, upon resolution of complaints,

resumed with a lower dose.

Virilization:
Patients should be informed about the potential occurrence of signs of virilization. In particular, singers and women with speech professions should be informed about the risk of deepening of the voice. The voice changes may be irreversible. If signs of virilisation develop, the risk/benefit ratio has to be newly assessed with the individual patient.

(Mis)use in sports:
Patients who participate in competitions governed by the World Anti-Doping Agency (WADA) should consult the WADA-code before using this product as SUSTANON can interfere with anti-doping testing. The misuse of androgens to enhance ability in sports carries serious health risks and is to be discouraged.

Drug abuse and dependence:
Testosterone has been subject to abuse, typically at doses higher than recommended for the approved indication(s) and in combination with other anabolic androgenic steroids. Abuse of testosterone and other anabolic androgenic steroids can lead to serious adverse reactions including: cardiovascular (with fatal outcomes in some cases), hepatic and/or psychiatric events. Testosterone abuse may result in dependence and withdrawal symptoms upon significant dose reduction or abrupt discontinuation of use. The abuse of testosterone and other anabolic androgenic steroids carries serious health risks and is to be discouraged.

Excipients:
SUSTANON contains arachis oil (peanut oil) and should not be taken/ applied by patients known to be allergic to peanut. As there is a possible relationship between allergy to peanut and allergy to soya, patients with soya allergy should also avoid Sustanon (see Section **4.3 Contraindications**).

SUSTANON contains 100 mg benzyl alcohol per ml solution and must not be given to premature babies or neonates. Benzyl alcohol may cause toxic reactions and anaphylactoid reactions in infants and children up to 3 years old.

4.5 Interactions with other medicines and other forms of interaction

Enzyme-inducing agents may decrease and enzyme-inhibiting drugs may increase testosterone levels. Therefore, adjustment of the dose of Sustanon may be required.

- **Insulin and other antidiabetic medicines:**
  Androgens may improve glucose tolerance and decrease the need for insulin or other anti-diabetic medicines in diabetic patients (see Section **4.4 Special Warnings and Precautions for use**). Patients with diabetes mellitus should therefore be monitored especially at the beginning or end of treatment and at periodic intervals during SUSTANON treatment.

Concomitant use of testosterone replacement therapy and sodium-glucose co-

transporter 2 (SGLT-2) inhibitors has been associated with an increased risk of erythrocytosis. Since both substances may independently elevate haematocrit levels, a cumulative effect is possible (see also section 4.4). Monitoring of haematocrit and haemoglobin levels is recommended in patients receiving both treatments.

- **Anti-coagulant therapy:**
  High doses of androgens may enhance the anti-coagulant action of coumarin-type agents (see Section **4.4 Special Warnings and Precautions for use**). Therefore close monitoring of prothrombin time and if necessary a dose reduction of the anti-coagulant is required during therapy.

- **ACTH or corticosteroids:**
  The concurrent administration of testosterone with ACTH or corticosteroids may enhance oedema formation; thus these active substances should be administered cautiously, particularly in patients with cardiac or hepatic disease or in patients predisposed to oedema (see Section **4.4 Special Warnings and Precautions for use**).

- **Paediatric population:**
  In pre-pubertal children statural growth and sexual development should be monitored since androgens in general and Sustanon in high dosages may accelerate epiphyseal closure and sexual maturation. (Also refer excipients below)

4.6 Fertility, pregnancy and lactation

Pregnancy
SUSTANON is contraindicated in women who are pregnant (see Section 4.3 Contraindications).

There are no adequate data for the use of SUSTANON in pregnant women. In view of the risk of virilization of the foetus, SUSTANON should not be used during pregnancy. Treatment with SUSTANON should be discontinued when pregnancy occurs.

Breast-feeding
There are no adequate data for the use of SUSTANON during lactation. Therefore, SUSTANON should not be used during lactation.

Fertility
In women, treatment with androgens can lead to an infrequent or repressed menstrual cycle (see Section 4.8 Undesirable effects).

In men, treatment with androgens can lead to fertility disorders by repressing sperm-formation (see Section 4.8 Undesirable effects).

4.7 Effects on ability to drive and use machines

SUSTANON has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Due to the nature of SUSTANON, side effects cannot be quickly reversed by discontinuing medication. Injectables in general, may cause a local reaction at the injection site.

The following adverse reactions have been associated with androgen therapy in general.

System Organ Class	MedDRA term*
Neoplasms benign, malignant and unspecified (incl. cysts and polyps)	Prostatic cancer[1]
Blood and lymphatic system disorders	Polycythaemia
Metabolism and nutrition disorders	Fluid retention, Weight increased
Psychiatric disorders	Depression, nervousness, mood altered, libido increased, libido decreased
Musculoskeletal and connective tissue disorders	Myalgia
Vascular disorders	Hypertension
Gastrointestinal disorders	Nausea
Hepatobiliary disorders	Hepatic function abnormal
Skin and subcutaneous tissue disorders	Pruritus, acne
Reproductive system and breast disorders	Gynaecomastia, oligozoospermia, priapism, Benign prostatic hyperplasia[2]
Investigations	Haematocrit increased Red blood cell count increased Haemoglobin increased Lipids abnormal[3], PSA increased

MedDRA version 15.0

[1] Progression of a sub-clinical prostatic cancer

[2] Prostatic growth (to eugonadal state)

[3] Decrease in serum LDL-C, HDL-C and triglycerides

The terms used to describe the undesirable effects above are also meant to include synonyms and related terms.

Adverse reactions from spontaneous reporting

In a few patients, diarrhoea and abdominal pain or discomfort have been reported during use of SUSTANON.

Treatment in women:

Treatment with SUSTANON may induce signs of virilization in women (see Section **4.4 Special Warnings and Precautions for use**). Symptoms of virilization may include hoarseness, acne, hirsutism, menstrual irregularity and alopecia.

Paediatric population:
The following undesirable effects have been reported in pre-pubertal children using androgens (see Section **4.4 Special Warnings and Precautions for use**): precocious sexual development, an increased frequency of erections, phallic enlargement and premature epiphyseal closure.

Drug abuse and dependence:
Testosterone, often in combination with other anabolic androgenic steroids (AAS), has been subject to abuse at doses higher than recommended for the approved indication (see Section **4.4 Special Warnings and Precautions for use**). The following additional adverse reactions have been reported in the context of testosterone/AAS abuse:

Endocrine disorders:
Secondary hypogonadism[1]

Psychiatric disorders:
Hostility, Aggression[1], Psychotic disorder[1], Mania, Paranoia and Delusion

Cardiovascular disorders:
Myocardial infarction[1], Cardiac failure[1], Cardiac failure chronic[1,2], Cardiac arrest, Sudden cardiac death, Cardiac hypertrophy[1,2], Cardiomyopathy[1], Ventricular arrhythmia, Ventricular tachycardia[1], Venous/arterial thrombotic and embolic events (including Deep Venous Thrombosis[1], Pulmonary Embolism[1], Coronary artery thrombosis, Carotid artery occlusion[1,2], Intracranial venous sinus thrombosis[1,2]), Cerebrovascular accident and Ischaemic stroke

Hepatobiliary disorders:
Peliosis hepatis[1], Cholestasis, Liver injury, Jaundice[1] and Hepatic failure

Skin and subcutaneous tissue disorders:
Alopecia[1]

Reproductive system and breast disorders:
Testicular atrophy, Azoospermia, Infertility (in males), Enlarged clitoris and Breast atrophy (in females)

Respiratory, thoracic and mediastinal disorders
Pulmonary oil microembolism: rare

Pulmonary microembolism of oily solutions can in rare cases lead to signs and symptoms such as cough, dyspnoea, malaise, hyperhydrosis, chest pain, dizziness, paresthesia, or syncope. These reactions may occur during or immediately after the injections and are reversible.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://pophealth.my.site.com/carmreportnz/s/.

[1] Has been reported with Sustanon
[2] With fatal outcomes in some cases

4.9 Overdose

The acute toxicity of testosterone is low. If symptoms of chronic overdose occur (e.g. polycythemia, priapism) treatment should be discontinued and after disappearance of the symptoms, be resumed at a lower dosage.

For risk assessment and advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Androgens. ATC code G03B A03.

Pharmacodynamic effects
Treatment of hypogonadal men with SUSTANON results in a clinically significant rise of plasma concentrations of testosterone, dihydrotestosterone, oestradiol and androstenedione, as well as a decrease of SHBG (sex hormone binding globulin). Luteinizing hormone (LH) and follicle-stimulating hormone (FSH) are restored to the normal range.

Clinical efficacy and safety
In hypogonadal men, treatment with SUSTANON results in an improvement of testosterone deficiency symptoms. Moreover, treatment increases bone mineral density and lean body mass, and decreases body fat mass. Treatment also improves sexual function, including libido and erectile function. Treatment decreases serum LDL-C, HDL-C and triglycerides, increases haemoglobin and hematocrit, whereas no clinically relevant changes in liver enzymes and PSA have been reported. Treatment may result in an increase in prostate size, but no adverse effects on prostate symptoms have been observed. In hypogonadal diabetic patients, improvement of insulin sensitivity and/or reduction in blood glucose have been reported with the use of androgens.

In female-to-male transsexuals, treatment with androgens/SUSTANON induces masculinization.

Paediatric population
In boys with constitutional delay of growth and puberty, treatment with androgens

accelerates growth and induces development of secondary sex characteristics.

5.2 Pharmacokinetic properties

SUSTANON 250 contains four esters of testosterone with different durations of action. The esters are hydrolyzed into the natural hormone testosterone as soon as they enter the general circulation.

Absorption
A single dose of SUSTANON 250 leads to an increase of total plasma testosterone with peak levels of approximately 70 nmol/l (C_{max}), which are reached approximately 24-48hrs (t_{max}) after administration. Plasma testosterone levels return to the lower limit of the normal range in males in approximately 21 days.

Distribution
Testosterone displays a high (over 97%) non-specific binding to plasma proteins and sex hormone binding globulin in in vitro tests.

Biotransformation
Testosterone is metabolized to dihydrotestosterone and oestradiol, which are further metabolized via the normal pathways.

Elimination
Excretion mainly takes place via the urine as conjugates of etiocholanolone and androsterone.

5.3 Preclinical safety data
Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Arachis (peanut) oil; benzyl alcohol.

6.2 Incompatabilities

Not applicable.

6.3 Shelf life

Shelf-life 60 months. SUSTANON may be used until the expiration date indicated on the package.

Store below 30°C; do not refrigerate or freeze. Store in original package and keep container in outer carton.

Ampoules: Since an opened ampoule cannot be resealed in such a way to further guarantee the sterility of the contents, the solution should be used immediately.

Vials: Single use in one patient only. The solution should be injected immediately after withdrawing the contents from the vial using a sterile syringe and needle.

6.4 Special precautions for storage

For storage conditions after first opening of the medicine, see section 6.3 Shelf life.

Discard any unused product or waste material.

6.5 Nature and contents of container

Each package contains one clear glass ampoule or one vial, containing 1 mL of oily solution for injection.

6.6 Special precautions for disposal

Any unused medicine or waste material should be disposed of in accordance with local requirements.

7. MEDICINE SCHEDULE

Prescription Medicine.

8. SPONSOR

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

Ph (09) 918 5100 Fax (09) 901 5101

9. DATE OF FIRST APPROVAL

31 December 1969

10. DATE OF REVISION OF THE TEXT

14 January 2026

SUMMARY TABLE OF CHANGES

Sections changed	Summary of new information
4.4, 4.5 & 4.8	New safety updates as a result of a PRAC recommendation concerning the increased risk: - in haemoglobin and haematocrit levels due to the drug-drug interaction between testosterone and SGLT-2 inhibitors. - between testosterone and pulmonary oil microembolism.
4.8 & 4.9	Text additions as per the Medsafe Data sheet template.