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SUSTANON® 250

Testosterone propionate,
Testosterone phenylpropionate,
Testosterone isocaproate,
Testosterone decanoate

Solution for injection

1. NAME OF MEDICINAL PRODUCT

Sustanon® 250, 250 mg/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sustanon 250 is a solution in oil. Each ampoule contains 1 ml arachis oil containing the following active substances:
- 30 mg testosterone propionate;
- 60 mg testosterone phenylpropionate;
- 60 mg testosterone isocaproate;
- 100 mg testosterone decanoate;

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

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

3. PHARMACEUTICAL FORM

Solution for injection.
A clear, pale yellow solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

In males: testosterone replacement therapy for primary or secondary hypogonadal disorders when testosterone deficiency has been confirmed by clinical features and biochemical tests, for example :
- after castration,
- eunuchoidism,
- hypopituitarism,
- endocrine impotence,
- certain types of infertility due to spermatogenic disorders,
- male climacteric symptoms such as decreased libido and decreased feeling of general well-being and fitness

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

4.2 Posology and method of administration

Usually one injection of 1 ml per 3 weeks is adequate.

Sustanon should be administered by deep intramuscular injection.
In general, the dose should be adjusted according to the response of the individual patient.

Safety and efficacy have not been adequately determined in children. Sustanon contains benzyl alcohol and should not be given to children under 3 years of age (see section 4.4 Special Warnings and Precautions for use).

4.3 Contraindications
- Known or suspected carcinoma of the prostate or breast (see section 4.4 Special warnings and precautions for use).
- Pregnancy
- Breast-feeding
- Hypersensitivity to the active substance or to any of the excipients, including arachis oil. Sustanon is therefore contraindicated in patients allergic to peanuts or soya (see section 4.4 Special warnings and precautions for use).

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 hemoglobin 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 preexisting 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.
- **Diabetes mellitus –** Androgens in general and Sustanon can improve glucose tolerance in diabetic patients (see section 4.5 Interaction with other medicinal products and other forms of interaction).
- **Anti-coagulant therapy** – Androgens in general and Sustanon can enhance the anti-coagulant action of coumarin-type agents (see also section 4.5 Interaction with other medicinal products 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.

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.

(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.

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.

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.

Elderly People:
There is limited experience on the safety and efficacy of the use of SUSTANON in patients over 65 years of age. Currently, there is no consensus about age specific testosterone reference values. However, it should be taken into account that physiologically testosterone serum levels are lower with increasing age.

4.5 Interaction with other medicinal products 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 anti-diabetic 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.

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).

Laboratory test interactions:
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.

4.6 Pregnancy, and lactation and fertility

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

There are no adequate data for the use of Sustanon during lactation.
Therefore, Sustanon should not be used during lactation.

Fertility:
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
Psychiatric disorders	Depression, Nervousness, Mood altered Libido increased Libido decreased
Vascular disorders	Hypertension
Gastrointestinal disorders	Nausea
Hepatobiliary disorders	Hepatic function abnormal
Skin and subcutaneous tissue Disorders	Pruritus Acne
Musculoskeletal and connective tissue disorders	Myalgia
Reproductive system and breast disorders	Gynaecomastia Oligozoospermia Priapism Benign prostatic hyperplasia[2]
Investigations	Lipids abnormal[3] PSA increased Haematocrit increased Red blood cell count increased Haemoglobin increased

[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.

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.

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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Androgens.
ATC code G03B A03
Treatment of hypogonadal men with Sustanon results in a clinically significant rise of plasma concentrations of testosterone, dihydrotestosterone, estradiol 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. 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, and increases hemoglobin 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 boys with constitutional delay of growth and puberty, treatment with Sustanon accelerates growth and induces development of secondary sex characteristics.

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AW Version: 2	**Page:** 1 of 2
New Item Code: 60002751	
Replacement: 30004027	
Market: Indonesia	
Product Name: Sustanon	
Number of Colours: 1	
BLACK	
Manufacturing Site: Ever Pharma	
Drawing Ref. Number: leaflet_148x420mm	
Drawing Version: 01	
Originated by: Sami Hajredin	
Originated at: Aspen Dandenong	
Originated on: 17-AUG-2022	
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160 mm Measuring Bar

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ID : EREG10021912300014

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 (Cmax), which are reached approximately 24-48 h (tmax) 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 estradiol, 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

Preclinical data with androgens in general reveal no hazards for humans. The use of androgens in different species has been demonstrated to result in virilization of the external genitals of female fetuses.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Arachis oil; benzyl alcohol.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life of Sustanon 250, under the given storage conditions, is 5 years.
Sustanon 250 may be used until the expiration date indicated on the package.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

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

6.6 Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.
See also "Special precautions for storage" and "Posology and method of administration".

Manufactured by :
EVER Pharma Jena GmbH, Germany

Registered by :
PT. Sydna Farma, Jakarta, Indonesia

Presentations:
Box, 1 ampoule @ 1 ml, Reg. No.: DKI1747200143A1

On Medical Prescription Only
Harus dengan resep dokter

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