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ML NOTARY SERVICES

Protocol No: 249/23

Destination: Chile

I, **MICHAEL LIGHTOWLER**, a duly appointed Notary Public of England and Wales **CERTIFY THAT** The Medicines and Healthcare Products Regulatory Agency in the United Kingdom has confirmed via the link below that the Certificate of a Pharmaceutical Product bearing No: **PP10181330** (of which the attached photostatically reproduced document is a true copy) was issued by them on 20th February 2023.

https://www.gov.uk/government/publications/human-medicines-register-of-electronic-export-certificates/register-of-electronic-export-certificates-issued-by-the-mhra-human-february-2023#contents

DIGITALLY SIGNED AND SEALED by me at Brentwood, Essex England this Twenty Fourth day of **March Two Thousand and Twenty Three**

Michael Lightowler

www.notaryservices.co.uk

Michael Lightowler LLB Notary Public
Cathedral Place, Brentwood, Essex CM14 4ES
t 01277 268333 - **e** ml@notaryservices.co.uk
Regulated through the Faculty Office of the Archbishop of Canterbury.

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Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

20th February 2023

Dear Applicant,

Electronic copies of Export certificates for medicines for humans

The MHRA will continue to issue Export Certificates as an electronic pdf copy. The certificates will be processed and signed electronically by MHRA named signatories. This cover letter will be attached to all submissions.

The authenticity of the certificates can be verified using the online register on our webpage: https://www.gov.uk/government/publications/human-medicines-register-of-electronic-export-certificates

Should you have any queries please contact us via e-mail: exports@mhra.gov.uk.

AJ

Asif Janjua
Head of Performance – Process Licensing
Medicines and Healthcare products Regulatory Agency

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Certificate Number: PP10181330

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

On behalf of the Department of Health

CERTIFICATE OF A PHARMACEUTICAL PRODUCT (1)

This certificate conforms to the format recommended by the World Health Organisation (explanatory notes are attached)

Exporting (certifying) country: **UNITED KINGDOM**

Importing (requesting) country: **CHILE**

1 Name and dosage form of the product:

A) In the United Kingdom - Sustanon 250, 250mg/ml Solution for Injection, SOLUTION FOR INJECTION

B) In CHILE - Sustenan 250, 250mg/1ml, Solution for Injection, SOLUTION FOR INJECTION

1.1 Active ingredient(s) (2) and amount(s) (3) per unit dose:

Active Ingredient(s)	Amount per unit dose
TESTOSTERONE PROPIONATE	30.000 MG
TESTOSTERONE DECANOATE	100.000 MG
TESTOSTERONE ISOCAPROATE	60.000 MG
TESTOSTERONE PHENYLPROPIONATE	60.000 MG

For complete qualitative composition including excipients, see attached. (4)

1.2 Is this product licensed to be placed on the market for use in the exporting country? (5) Yes

1.3 Is this product actually on the market in the exporting country? Yes

1.4 The product is not on the market in the exporting country because

N/A

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2A.1 Product Licence/Marketing Authorisation

Number [7]: **PL 39699/0059**
Date of Issue: 09 April 2014

2A.2 The name and address of the Product Licence/Marketing Authorisation holder are:

Name: ASPEN PHARMA TRADING LIMITED

Address: 3016 LAKE DRIVE, CITYWEST BUSINESS CAMPUS, DUBLIN 24, IRELAND

2A.3 Status of the Product Licence/Marketing Authorisation holder [8]:

c) is not involved in manufacturing, packaging or labelling the dosage form but is responsible for the quality and release of the product

2A.3.1 For categories b,c and d the names and address of the manufacturing site where the dosage form is produced are [9]:

See attached page for Manufacturers/Packagers

2A.4 Is Summary Basis of Approval appended? [10] No

2A.5 Is the attached, officially approved product information complete and consonant with the licence? [11] Yes

2A.6 Applicant for certificate, if different from licence holder (name and address) [12]:

Name:

Address:

Section 2B is not included because the product named in this certificate is licensed in the UK[6]

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3	Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? (14)	N/A

IF NO OR NOT APPLICABLE PROCEED TO QUESTION 4

3.1	Periodicity of routine inspections (years)	
3.2	Has the manufacturer of this type of dosage form been inspected?	
3.3	Do the facilities and operations conform to GMP as recommended by the World Health Organisation ? (15)	
4	Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product including Good Manufacturing Practice (GMP)? (16)	Yes
	If No, explain	

Additional Information:

NONE

Address of certifying authority:

The Medicines and Healthcare products Regulatory Agency,
10 South Colonnade, Canary Wharf, London E14 4PU, United Kingdom

Telephone Number: +44 (0) 20 3080 6593

Name of authorised person: Colin Atkinson

Signature: 

Stamp and Date: 20 February 2023

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Names and Addresses of Manufacturers/Packagers (9)

Manufacturers

Name:	EVER PHARMA JENA GMBH
Address:	OTTO-SCHOTT-STRASSE 15, JENA, D-07745, GERMANY

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Excipient	Modifier	Amount per unit dose
REFINED ARACHIS OIL		1.000 ML
BENZYL ALCOHOL		0.100 ML

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Explanatory Notes

1. This certificate, which is in the form recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the UK. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.

2. Whenever possible International Non-proprietary Names (Inns) or national non-proprietary names have been used.

3. The formula (complete composition) of the dosage form should be given on the certificate or be appended.

4. Details of the quantitative composition are preferred but their provision is subject to the agreement of the Marketing Authorisation holder.

5. When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the Marketing Authorisation.

6. Sections 2A and 2B are mutually exclusive.

7. Indicate when applicable if the licence is provisional or the product has not yet been approved.

8. Specify whether the person responsible for placing the product on the market:

   (a) manufactures the dosage form and is responsible for the quality assurance and release of the product.
   (b) packages and/or labels a dosage form manufactured by another company but is responsible for the quality assurance and release of the product.
   (c) is not involved in manufacturing, packaging or labelling the dosage form but is responsible for the quality and release of the product.
   (d) is involved in none of the above.

9. This information is optional and can be provided only with the permission of the product-licence holder or, in the case of non-registered products, the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information.

   It should be noted that:

   information concerning the site of manufacture is part of the Marketing Authorisation. If the manufacturing site is changed the licence must be updated or it will cease to be valid.

   in the UK manufacture of pharmaceutical products is only permitted on licensed manufacturing sites. When the product-licence holder or applicant conforms to status (b), (c) or (d) as described in note 8 above the Manufacturing Licence holder is responsible for the manufacture of the dosage form.

10. This refers to the document prepared by some national regulatory authorities that summarises the technical basis on which the product has been licensed. The UK Medicines and Healthcare products Regulatory Agency does not prepare such a document.

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11. This refers to product information approved by the Medicines and Healthcare products Regulatory Agency such as a Summary of Product Characteristics (SPC).

12. In this circumstance permission for issuing the certificate is required from the Marketing Authorisation holder. This permission must be provided to the Medicines and Healthcare products Regulatory Agency by the applicant.

13. Please indicate the reason that the applicant has provided for not requesting registration:

    (a) the product has been developed exclusively for the treatment of conditions - particularly tropical diseases - not endemic in the UK.
    (b) the product has been reformulated with a view to improving its stability under tropical conditions.
    (c) the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the UK.
    (d) the product has been reformulated to meet a different maximum dosage limit for an active ingredient.
    (e) this type of product does not require a Marketing Authorisation in the UK.
    (f) any other reason.

14. "Yes" means the Medicines and Healthcare products Regulatory Agency arranges periodic inspections of the manufacturing plant in which the dosage form is produced. "No" means that manufacture is taking place in a country other than the UK and inspections are not carried out by any Regulatory Authority. "Not applicable" means that manufacture is taking place in a country other than the UK and inspection is conducted under the aegis of the country of manufacture.

15. The requirements of good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty second report of the Expert Committee on Specifications for Pharmaceutical Preparations (WHO Technical Report Series, No. 823, 1992, Annex 1). Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardisation (WHO Technical Report Series No. 822, 1992, Annex 1).

16. This section is to be completed when the product-licence holder or applicant conforms to status (b), (c) or (d) as described in note 8 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form and the extent and nature of any controls exercised over each of these parties.

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Certificate Number: PP10181330

SUMMARY OF PRODUCT CHARACTERISTICS

Printed for Certificate of Pharmaceutical Product

1 NAME OF THE MEDICINAL PRODUCT

Sustanon 250, 250mg/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 components 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.

3 PHARMACEUTICAL FORM

Solution for injection
A clear, pale yellow solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Testosterone replacement therapy for male hypogonadism, when testosterone deficiency has been confirmed by clinical features and biochemical tests.
Testosterone administration may also be used as supportive therapy for female-to-male transsexuals.

4.2 Posology and method of administration

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

Adults (incl. elderly):
Usually, one injection of 1ml per 3 weeks is adequate.

Paediatric population:
Safety and efficacy have not been adequately determined in children and adolescents. Pre-pubertal children treated with Sustanon 250 should be treated with caution (see section 4.4).

Female-to-male transsexuals:
Different specialist centres have used doses varying from one injection of 1ml every two weeks to one injection of 1ml every four weeks.

Method of administration
Sustanon 250 should be administered by deep intramuscular injection.

4.3 Contraindications

- Pregnancy (see section 4.6).
- Known or suspected carcinoma of the prostate or breast (see section 4.4.).
- Breast-feeding.

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SUMMARY OF PRODUCT CHARACTERISTICS

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- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1, including arachis oil. Sustanon 250 is therefore contraindicated in patients allergic to peanuts or soya (see section 4.4).

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 250 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),
- Haematocrit and haemoglobin to exclude polycythaemia.

In patients receiving long-term androgen therapy, the following laboratory parameters should also be monitored regularly: haemoglobin, and haematocrit, liver function tests and lipid profile.

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 hypercalcaemia or hypercalciuria may develop spontaneously, also during androgen therapy. The latter can be indicative of a positive tumour response to the hormonal treatment. Nevertheless, the hypercalcaemia or hypercalciuria should first be treated appropriately and after restoration of normal calcium levels, hormone therapy can be resumed.

- **Pre-existing conditions** – In patients suffering from severe cardiac, hepatic or renal insufficiency or ischaemic heart disease, treatment with testosterone may cause severe complications characterised by oedema with or without congestive cardiac 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.

  Testosterone may cause a rise in blood pressure and Sustanon 250 should be used with caution in men with hypertension.

- **Epilepsy or Migraine** – (or a history of these conditions), since androgens may occasionally induce fluid and sodium retention.

- **Diabetes mellitus** – Androgens in general and Sustanon 250 can improve glucose tolerance in diabetic patients (see section 4.5).

- **Anti-coagulant therapy** – Androgens in general and Sustanon 250 can enhance the anti-coagulant action of coumarin-type agents (see also section 4.5).

- **Sleep apnoea** – Caution should be applied when treating men with sleep apnoea. There have been reports that testosterone can cause or exacerbate pre-existing sleep apnoea. However, there is a lack of evidence

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regarding the safety of testosterone in men with the condition. 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), treatment with Sustanon 250 should be discontinued and, upon resolution of complaints, resumed with a lower dose.

Virilisation:
Patients should be informed about the potential occurrence of signs of virilisation. 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 250 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 250 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 250 (see section 4.3).

Sustanon 250 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.

Female-to-male transsexual supportive therapy:
Before initiating Sustanon 250 for female-to-male transsexuals, specialist assessment should be undertaken, including psychiatric assessment. A complete personal and medical history should be taken. During treatment, periodic check-ups are recommended of a frequency and nature adapted to the individual. The following should be monitored:

- signs of osteoporosis,
- changes in lipid profile.

In patients with a personal or family history of breast cancer and with a personal history of endometrial cancer, careful monitoring should be undertaken.

Subject to specialist advice, hysterectomy and bilateral oophorectomy should be considered after 18-24 months of testosterone treatment, to reduce the possible increased risk of endometrial and ovarian cancer.

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Continued surveillance is required to detect osteoporosis in patients who have undergone oophorectomy, as testosterone may not fully reverse the decline in bone density in these patients.

Continued surveillance is required to detect endometrial and ovarian cancer in patients on long term treatment who have not proceeded to hysterectomy and bilateral oophorectomy.

Paediatric population
In pre-pubertal children statural growth and sexual development should be monitored since androgens in general and Sustanon 250 in high dosages may accelerate epiphyseal closure and sexual maturation.

Older People:
There is limited experience on the safety and efficacy of the use of Sustanon 250 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.

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.

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 250 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).
Patients with diabetes mellitus should therefore be monitored especially at the beginning or end of treatment and at periodic intervals during Sustanon 250 treatment.

Anti-coagulant therapy:
High doses of androgens may enhance the anticoagulant action of coumarin type agents (see section 4.4). 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 therefore 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).

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, and there is no clinical evidence of thyroid dysfunction.

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4.6 Fertility, pregnancy and lactation

Sustanon 250 is contra-indicated in women who are pregnant (see section 4.3).

Pregnancy

There are no adequate data for the use of Sustanon 250 in pregnant women. In view of the risk of virilisation of the foetus, Sustanon 250 should not be used during pregnancy (see section 4.3). Treatment with Sustanon should be discontinued when pregnancy occurs.

Breastfeeding

There are no adequate data for the use of Sustanon 250 during lactation. Therefore, Sustanon 250 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).

In women treatment with androgens can lead to an infrequent or repressed menstrual cycle (see section 4.8).

4.7 Effects on ability to drive and use machines

Sustanon 250 has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Due to the nature of Sustanon 250 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.

All adverse reactions are listed by system organ class and frequency; common (≥ 1/100 to < 1/10) and not known (cannot be estimated from the available data).

System Organ Class	MedDRA term	Frequency
Neoplasms benign, malignant and unspecified (incl. cysts and polyps)	Prostatic cancer[1]	Not known
Blood and lymphatic system disorders	Polycythaemia	Not known
Metabolism and nutrition disorders	Fluid retention	Not known
	Weight increased	Common
Psychiatric disorders	Depression, Nervousness Mood altered Libido increased, Libido decreased	Not known
Vascular disorders	Hypertension	Not known

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Gastrointestinal disorders	Nausea	Not known
Hepatobiliary disorders	Hepatic function abnormal	Not known
Skin and subcutaneous tissue disorders	Pruritus Acne	Not known
Musculoskeletal and connective tissue disorders	Myalgia	Not known
Reproductive system and breast disorders	Ejaculation disorder Gynaecomastia Oligospermia Priapism Benign prostatic hyperplasia[2]	Not known
Investigations	Lipids abnormal[3] PSA increased Haematocrit increased Red blood cell count increased Haemoglobin increased	Not known Common

[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.

Treatment in women

Treatment with Sustanon 250 may induce signs of virilisation in women (see section 4.4). Symptoms of virilisation may include hoarseness, acne, hirsutism, menstrual irregularity and alopecia.

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Paediatric population
The following undesirable effects have been reported in prepubertal children using androgens (see section 4.4): precocious sexual development, an increased frequency of erections, phallic enlargement and premature epiphyseal closure.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

The acute toxicity of testosterone is low.

If symptoms of chronic overdose occur (e.g. polycythaemia, priapism) treatment should be discontinued and after disappearance of the symptoms, be resumed at lower dosage.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Androgens. ATC code G03B A03

Treatment of hypogonadal men with Sustanon 250 results in a clinically significant rise of plasma concentrations of testosterone, dihydrotestosterone, estradiol and androstenedione, as well as 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 250 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 haemoglobin and haematocrit, which may lead to polycythaemia. No clinically relevant changes in liver enzymes and PSA have been reported. Testosterone also produces systemic effects, such as increasing the retention of sodium, potassium and chloride leading to an increase in water retention. Treatment may result in an increase in prostate size, and worsening of lower urinary tract symptoms, but no adverse effects on prostate symptoms have been observed. In hypogonadal diabeteic patients, improvement of insulinsensitivity 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 250 accelerates growth and induces development of secondary sex characteristics. In female-to-male transsexuals, treatment with Sustanon 250 induces masculinisation.

5.2 Pharmacokinetic properties

Sustanon 250 contains four esters of testosterone with different durations of action. The esters are hydrolysed 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 70nmol/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.

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In female-to-male transsexuals, a single dose of Sustanon 250 repeated every two weeks resulted in mean trough testosterone levels towards the upper end of the normal male range at 2, 4 and 12 months.

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 metabolised to dihydrotestosterone and estradiol, which are further metabolised 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 hazard for humans. The use of androgens in different species has been demonstrated to result in virilisation of the external genitals of female foetuses.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Arachis Oil

Benzyl Alcohol

6.2 Incompatibilities
Not applicable

6.3 Shelf life
5 years

6.4 Special precautions for storage
Store below 30°C
Do not refrigerate or freeze
Store in the original package in order to protect from light

6.5 Nature and contents of container
Each colourless glass ampoule is filled with 1 ml of Sustanon 250.
A box of Sustanon 250 contains 1 ampoule.
Not all pack sizes may be marketed. In correspondence please quote batch number.

6.6 Special precautions for disposal and other handling
Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

ASPEN PHARMA TRADING LIMITED
3016 LAKE DRIVE
CITYWEST BUSINESS CAMPUS
DUBLIN 24
IRELAND

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SUMMARY OF PRODUCT CHARACTERISTICS

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8 MARKETING AUTHORISATION NUMBER(S)

PL 39699/0059

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28/02/1973
Date of latest renewal: 29/11/2002

10 DATE OF REVISION OF THE TEXT

14/12/2022