1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

SUSTANON 250 injection

Testosterone

Sugar free

Read all this leaflet carefully before you are given SUSTANON 250

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

1. What SUSTANON 250 is and what it is used for
2. What you need to know before you are given SUSTANON 250
3. How to be given SUSTANON 250
4. Possible side effects
5. How to store SUSTANON 250
6. Contents of the pack and other information

1. What SUSTANON 250 is and what it is used for

SUSTANON 250 contains the active substance testosterone.

SUSTANON 250 belongs to a group of medicines called anabolic steroids.

SUSTANON 250 is used in adult men for testosterone replacement to treat lack of testosterone (male hypogonadism). Your doctor will confirm this by blood testosterone measurements and also clinical symptoms such as inability to get or maintain an erection (impotence), infertility, low sex drive, tiredness, depressive moods, or bone loss caused by low hormone levels.

2. What you need to know before you receive SUSTANON 250

SUSTANON 250 should not be administered to you:

- if you are hypersensitive (allergic) to testosterone or any of the other ingredients of SUSTANON 250 (listed in section 6).
- if you have or have had a tumour of your prostate or breast or are suspected to have one of these tumours.
- if you are allergic to peanuts or soya.
- if you are pregnant or think you may be pregnant or if you are breastfeeding (see section 2: Pregnancy, breastfeeding and fertility).

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection:

Take special care with SUSTANON 250:

- as 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 and blood tests for prostate-specific antigen.

- as additionally, at regular intervals, blood tests will be done to your red blood cells (haemoglobin) as SUSTANON 250 may increase your red blood cell levels leading to complications such as bleeding and clotting problems, such as strokes and heart attacks.
- as your doctor will measure testosterone blood levels before and during your treatment. Based on the blood test results, your doctor may adjust the dose of SUSTANON 250.
- as medical checks may also be necessary in some other conditions. Therefore, tell your doctor if you have or have ever had:
  - any cancer
  - heart disease
  - kidney disease
  - liver disease
  - high blood pressure
  - diabetes mellitus
  - epilepsy
  - migraine headaches
  - prostatic complaints, such as problems with passing urine
- If you have or ever had blood clotting problems (thrombophilia) (an abnormality of blood coagulation that increases the risk of thrombosis - blood clots in blood vessels):
  - *Factors that increase your risk for blood clots in a vein:* previous blood clots in a vein; smoking; obesity; cancer; immobility; if one of your immediate family has had a blood clot in the leg, lung or other organ at a young age (e.g. below the age of about 50); or as you get older.

- *How to recognise a blood clot:* painful swelling of one leg or sudden change in colour of the skin e.g. turning pale, red or blue, sudden breathlessness, sudden unexplained cough which may bring up blood; or sudden chest pain, severe light headedness or dizziness, severe pain in your stomach, sudden loss of vision.
- Seek urgent medical attention if you experience one of these symptoms.

If you are obese and you have chronic obstructive lung disease, SUSTANON 250 may cause you to stop breathing while you sleep (sleep apnoea).

SUSTANON 250 should not be used to enhance ability in sports performance as it carries serious health risks.

SUSTANON 250 affects glucose tolerance. If you are diabetic, you may need a lower dose of insulin or anti-diabetic medication.

If you notice any signs of masculinisation (for instance lowering of the voice or increase in body or facial hair), consult your doctor immediately.

Children and adolescents

The safety and efficacy of SUSTANON 250 has not been determined in children and adolescents.

The elderly

There is limited experience on the safety and efficacy of the use of SUSTANON 250 in patients over 65 years of age.

Other medicines and SUSTANON 250

Always tell your healthcare professional if you are taking any other medicines (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

- Rifampicin (an antibiotic).
- Medicines for epilepsy or sleeplessness.
- Insulin and/or other medicines to control blood sugar levels (such as glibenclamide), as SUSTANON 250 may affect glucose tolerance and decrease the need for insulin or other anti-diabetic medicines if you are diabetic.
- Medicines to reduce the clotting of your blood (anti-coagulants such as warfarin), as SUSTANON 250 may increase the anticoagulant action of some anticoagulants. Your doctor may have to reduce the dose of the anticoagulants and will check your INR more frequently.
- The hormone ACTH or corticosteroids (used to treat various conditions such as rheumatism, arthritis, allergic conditions and asthma). The use of SUSTANON 250 may increase the risk of water retention especially if your heart and liver are not working properly.
- SUSTANON 250 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 SUSTANON 250.

SUSTANON 250 with food and drink

Since SUSTANON 250 is administered intramuscularly, interactions with food, drinks or physical activity are not likely.

Pregnancy, breastfeeding and fertility

You should not receive SUSTANON 250 if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

SUSTANON 250 is not indicated for use in women.

In men, treatment with SUSTANON 250 can lead to fertility disorders by suppressing sperm formation.

Driving and using machines

SUSTANON 250 may affect your ability to drive or use machines.
You should not drive, use machinery or perform any tasks that require concentration until you are certain that SUSTANON 250 does not adversely affect your ability to do so safely (see section 4).

SUSTANON 250 contains arachis oil and benzyl alcohol *10* % *v/v*

SUSTANON 250 contains arachis oil, which is a peanut oil. Therefore, if you are allergic to peanuts or soya you should not take this medicine.

This medicine contains benzyl alcohol 10 % *v/v.* Medicines containing benzyl alcohol must not be given to premature babies or neonates. Benzyl alcohol may cause toxic reactions and allergic reactions in infants and children up to 3-year-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 SUSTANON 250 as SUSTANON 250 can interfere with anti-doping testing.

The misuse of this medicine to enhance ability in sports carries serious health risks.

Drug abuse and dependence

SUSTANON 250 should only be given by a doctor or nurse and used exactly as your doctor has told you. Abuse of testosterone, especially if you use too much of this medicine alone or with other anabolic androgenic steroids, can cause serious health problems to your heart and blood vessels (that can lead to death), mental health and/or the liver. Individuals who have abused testosterone may become dependent and experience withdrawal symptoms when the dosage changes significantly or is stopped immediately. You should not abuse SUSTANON 250 alone or with other anabolic androgenic steroids because it carries serious health risks.

3. How SUSTANON 250 is given

SUSTANON 250 injection should only be given by a doctor or nurse.

Always receive SUSTANON 250 exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

If you have the impression that the effect of SUSTANON 250 is too strong or too weak for you, tell your doctor or pharmacist.

You will not be expected to give yourself SUSTANON 250. It will be given to you by a person who is qualified to do so.

When to receive SUSTANON 250

Adults

The usual dosage is one injection of 1 ml every 3 weeks.

The injections are given deeply into a muscle (for instance in the buttock, upper leg or upper arm).

Please note: An opened ampoule cannot be resealed in such a way that guarantees that the contents stay sterile. Therefore, the injection fluid should be used immediately after opening an ampoule.

Use in children and adolescents

The safety and efficacy of SUSTANON 250 have not been determined in children and adolescents (see section 2: Warnings and precautions).

If you are given more SUSTANON 250 than you should

Since a healthcare professional will administer SUSTANON 250, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you have swallowed SUSTANON 250 should consult a doctor.

If you forget to receive your injection of SUSTANON 250

Do not receive a double dose to make up for forgotten individual doses. Since a healthcare provider will administer SUSTANON 250, it is unlikely that the dose will be missed.

4. Possible side effects

SUSTANON 250 can have side effects.

Not all side effects reported for SUSTANON 250 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving SUSTANON 250, please consult your healthcare provider for advice.

If any of the following happens, stop receiving SUSTANON 250 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching (pruritus).

These are all very serious side effects. If you have them, you may have had a serious reaction to SUSTANON 250. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Side effects with an unknown frequency

- acne,
- nausea,
- changes in liver function tests,
- changes in cholesterol levels (changes in lipid metabolism),
- depression, nervousness, mood disturbances, aggression,
- muscle pain (myalgia),
- fluid retention in the tissues, usually marked by swelling of ankles or feet,
- high blood pressure (hypertension),
- increase in the number of red blood cells (cells which carry the oxygen in your blood),
- increase in percentage of red blood cells relative to the total blood volume (haematocrit),
- increased concentration of the red blood cell component that carries oxygen (haemoglobin),
- changes in sexual desire,
- prolonged abnormal, painful erection of the penis,
- disturbed formation of sperm,
- development and enlargement of breasts in males, prostatic growth, with increased in size and weight of prostate, increased levels of a blood marker which is associated with prostate cancer (PSA increased),
- increased growth of a prostate cancer.

Due to the nature of SUSTANON 250, side effects cannot be quickly reversed by discontinuing medication.

Injectables in general, may cause local reaction at the injection site.

Side effects in women

In women, this medicine may induce signs of masculinisation (for example, lowering of the voice, and increase in body or facial hair.)

Children and adolescents

The following side effects have been reported in pre-pubertal children using SUSTANON 250:

- early sexual development,
- penis enlargement,
- an increased frequency of erections,
- growth limitation (limited body height).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to **SAHPRA:** via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's Publications:

https://www.sahpra.org.za/Publications/Index/8

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of SUSTANON 250.

5. How to store SUSTANON 250

Store all medicines out of reach of children.

Keep SUSTANON 250 in the original box in a safe place.

Observe the storage conditions given below and on the box.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

SUSTANON 250 Injection should be stored at or below 30 °C. Do not refrigerate or freeze.

Store in the original package in order to protect from light.

Return unused medicines to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SUSTANON 250 contains

The active substance is 250 mg of testosterone. Each ampoule of SUSTANON 250 contains 1 ml arachis oil containing the following active substances: testosterone propionate 30 mg, testosterone phenylpropionate 60 mg, testosterone isocaproate 60 mg, testosterone decanoate 100 mg.

The other ingredients are arachis oil and benzyl alcohol 10 % *v/v.*

Sugar free

What SUSTANON 250 looks like and contents of the pack

Box of 1 ml clear glass ampoule packed as a single unit.

An ampoule marked with a red and yellow ring on the neck, containing a clear yellow oily solution.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 118 088

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G3208 (Act 101/1965)

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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