Sustanon 250®

COMPOSITION:
Each ml contains:

Testosterone Decanoate (BP 2005 grade) 100 mg
Testosterone Isocaproate (BP 2005 grade) 60 mg
Testosterone Phenylpropionate (BP (vet) 2005 grade) 60 mg
Testosterone Propionate (USP29, Ph.Eur.5.5 grade) 30 mg
Miglyol 840
Ethyl oleate
Benzyl benzoate
Benzyl alcohol

DESCRIPTION:
Chemical Name: 17ß-hydroxyandrost-4-en-3-one
Molecular Formula: $C_{19}H_{28}O_2$
Molecular Weight: 288.429 gm/mol
Active life: up to 3 weeks
Detection time: more than 3 months
Anabolic/Androgenic ratio: 100/100

Sustanon250® is an androgenic preparation for intramuscular administration containing four different esters of the natural hormone testosterone.
Sustanon250® contains a hormone which is similar to the hormone testosterone that is produced by the body. Testosterone is a male sex hormone that is responsible for the development of male characteristics. These include growth of hair on the face and body, deepening of the voice, muscle development and the development of the male genitalia. Testosterone is also important for maintaining the strength of bones, libido and fertility in men. Men who do not produce enough testosterone may be prone to problems such as decreased libido, infertility or osteoporosis. In men who do not produce enough testosterone, Sustanon250® is used to reduce the effects of a low level of testosterone. People who have a female to male gender reassignment procedure may need to take Sustanon250® to help strengthen male characteristics.

CLINICAL PHARMACOLOGY:
Testosterone and dihydrotestosterone are responsible for normal growth and development of the male sex organs and for maintenance of secondary sex characteristics. These effects include the growth and maturation of the prostate, seminal vesicles, penis, and scrotum; the development of male hair distribution, such as facial, pubic, chest, and axillary hair; laryngeal enlargement; vocal cord thickening; alterations in body musculature; and fat distribution and have been reported to stimulate the production of red blood cells by enhancing the production of erythropoietic stimulating factor.

Male hypogonadism results from insufficient secretion of testosterone and is characterized by low serum testosterone concentrations. Symptoms associated with male hypogonadism include decreased sexual desire with or without impotence, fatigue and loss of energy, mood depression, regression of secondary sexual characteristics, and osteoporosis. Hypogonadism is a risk factor for osteoporosis in men. Androgens have been reported to increase protein anabolism and decrease protein catabolism. Nitrogen balance is improved only when there is sufficient intake of calories and protein.

During exogenous administration of androgens, endogenous testosterone release may be inhibited through feedback inhibition of pituitary luteinizing hormone (LH). At large doses of exogenous androgens, spermatogenesis may also be suppressed through feedback inhibition of pituitary follicle-stimulating hormone (FSH).

Esterification of testosterone at position 17 increases the lipid solubility of the testosterone molecule and prolongs the activity of the molecule by increasing its residence time. Following intramuscular administration in an oily vehicle, testosterone ester is slowly absorbed into the circulation and rapidly hydrolyzed in plasma to testosterone. In a study of healthy males, a single injection of 200 mg of Testosterone Cypionate increased mean serum testosterone concentrations sharply to 3 times the basal levels (approximately 1350 ng/dl) at 24 hours and declined gradually to basal levels (approximately 500 ng/dl) by day 10.

Circulating testosterone is chiefly bound in the serum to sex hormone-binding globulin (SHBG) and albumin. Testosterone is metabolized to various 17-keto steroids through two different pathways. The major active metabolites of testosterone are estradiol and dihydrotestosterone.

INDICATIONS AND USAGE:
Testosterone replacement therapy in male hypogonadal disorders, for example: After castration, Eunuchoidism, Hypopituitarism.

CONTRAINDICATIONS:
• Known or suspected mammary or prostatic carcinoma in the male. This medicine is not intended for use in female patients.
• This preparation is also contraindicated in patients with a history of hypersensitivity to any of its components.
• Woman who are or may become pregnant
• Benign prostatic hyperplasia with obstruction
• Undiagnosed genital bleeding
• Severe kidney and heart failure

PRECAUTIONS:
If an androgen-associated adverse reaction occurs, treatment should be interrupted and, after disappearance of the symptoms, be resumed at a lower dosage. Patients with latent or overt cardiac failure, renal dysfunction, hypertension, epilepsy or migraine (or a history of these conditions) should be monitored, since androgens may occasionally induce salt and fluid retention. Androgens should be used cautiously in pre-pubertal boys to avoid premature epiphyseal closure or precocious sexual development. A decrease in protein bound iodine (PBI) may occur, but this has no clinical significance. Treatment of male patients over the age of approximately 50 years with androgens should be preceded by a thorough examination of prostate and baseline measurement of prostate-specific antigen serum concentration.

WARNINGS: Middle-aged and elderly males with angina pectoris or other severe circulatory disease should receive androgen treatment only under very careful supervision.

LIVER CELL TUMORS ARE REPORTED. MOST OFTEN THESE TUMORS ARE BENIGN AND ANDROGEN DEPENDENT, BUT FATAL MALIGNANT TUMORS HAVE BEEN REPORTED. WITH DRAWAL OF DRUG OFTEN RESULTS IN REGRESSION OR CESSATION OF PROGRESSION OF THE TUMOR. HOWEVER, HEPATIC TUMORS ASSOCIATED WITH ANDROGENS OR ANABOLIC STEROIDS ARE MUCH MORE VASCULAR THAN OTHER HEPATIC TUMORS AND MAY BE SILENT UNTIL LIFE-THREATENING INTRA-ABDOMINAL HEMORRHAGE DEVELOPS.
PELIOSIS HEPATIS, A CONDITION ARE ALSO REPORTED IN WHICH LIVER AND SOMETIMES SPLENIC TISSUE IS REPLACED WITH BLOOD-FILLED CYSTS, HAS BEEN REPORTED IN PATIENTS RECEVING ANDROGENIC ANABOLIC STEROID THERAPY. THESE CYSTS ARE SOMETIMES PRESENT WITH MINIMAL HEPATIC DYSFUNCTION, BUT AT OTHER TIMES THEY HAVE BEEN ASSOCIATED WITH LIVER FAILURE. THEY ARE OFTEN NOT RECOGNIZED UNTIL LIFE-THREATENING LIVER FAILURE OR INTRA-ABDOMINAL HEMORRHAGE DEVELOPS. WITHDRAWAL OF DRUG USUALLY RESULTS IN COMPLETE DISAPPERRANCE OF LESIONS.
BLOOD LIPID CHANGES THAT ARE KNOWN TO BE ASSOCIATED WITH INCREASED RISK OF ATHEROSCLEROSIS ARE SEEN IN PATIENTS TREATED WITH ANDROGENS AND ANABOLIC STEROIDS. THESE CHANGES INCLUDE DECREASED HIGH-DENSITY LIPOPROTEIN AND SOMETIMES INCREASED LOW-DENSITY LIPOPROTEIN. THE CHANGES MAY BE VERY MARKED AND COULD HAVE A SERIOUS IMPACT ON THE RISK OF ATHEROSCLEROSIS AND CORONARY ARTERY DISEASE.

SIDE EFFECTS:
A medicine is only made available to the public if the clinical trials have shown that the benefits of taking the medicine outweigh the risks. Once a medicine has been licensed, information on the medicine's effects, both intended and unintended, is continuously recorded and updated. Some side effects may be serious while others may only be a mild inconvenience. Everyone's reaction to a medicine is different. It is difficult to predict which side effects you will have from taking a particular medicine, or whether you will have any side effects at all. The important thing is to tell your prescriber or pharmacist if you are having problems with your medicine.
The frequency of these side effects is unknown
• abnormal laboratory test results
• acne
• blood problems
• breast enlargement in men
• cancer of the prostate
• changes in glucose tolerance
• changes in libido
• decreased need for insulin or other antidiabetic medicines in people who have diabetes
• depression
• ejaculation problems
• feeling nervous
• fluid retention
• injection site problems
• itching
• may affect the results for certain tests
• metabolic problems
• mood changes
• more frequent erections, an enlarged penis or early sexual development may occur in boys who have not started to go through puberty you must seek medical advice if any of these happen to you
• muscle pain or tenderness
• nausea
• premature epiphyseal closure this may occur in boys who have not started to go through puberty
• priapism you must seek medical advice if this happens to you
• prostate problems
• raised blood pressure
• reduced sperm production
If you feel unwell or if you have concerns about a Side effect, you will need to seek advice. If you feel very ill, get medical help straight away. Contact your prescriber, pharmacist or nurse.

DRUG INTERACTIONS:
If you are taking more than one medicine they may interact with each other. At times your prescriber may decide to use medicines that interact; in other cases this may not be appropriate. The decision to use medicines that interact depends on your specific circumstances. Your prescriber may decide to use medicines that interact, if it is believed that the benefits of taking the medicines together outweigh the risks. In such cases, it may be necessary to alter your dose or monitor you more closely. Tell your prescriber the names of all the medicines that you are taking so that they can consider all possible interactions. This includes all the medicines which have been prescribed by your GP, hospital doctor, dentist, nurse, health visitor, midwife or pharmacist. You must also tell your prescriber about medicines which you have bought over the counter without prescriptions.
The following types of medicine may interact with Sustanon250®:
• Liver enzyme inducers
• Liver enzyme inhibitors
• Coumarin anticoagulants
• Antidiabetic agent oral or insulin.
• Cyclosporine
• Human growth hormone (Somatropin)

If you are taking Sustanon250® and one of the above types of medicines, make sure your prescriber knows about it.

ADVERSE REACTIONS:

Male: Gynecomastia, excessive frequency and duration of penile erections, oligospermia.
Skin and Appendages: Hirsutism, male pattern baldness and acne, gynecomastia.
Fluid/electrolyte Disturbances: Retention of sodium, chloride, water, potassium, calcium, and inorganic phosphates.
Gastrointestinal: Nausea, cholestatic jaundice, alterations in liver function tests; rarely, hepatocellular neoplasms, peliosis hepatitis, hepatic adenomas, and cholestatic hepatitis.
Hematologic: Suppression of clotting factors II, V, VII, & X; bleeding in patients on anti-coagulant therapy.
Nervous System: Increased or decreased libido, headache, anxiety, depression, and generalized paresthesia.
Other: Serum lipid changes, hypercalcaemia, hypertension, oedema, priapism, and potentiation of sleep apnea.

OVERDOSAGE:
There have been no reports of acute overdosage with the androgens.

PATIENT MONITORING:
• Bone age determinations
• Cholesterol and/or HDL and LDL
• Hemoglobin and Hematocrit determinations
• Hepatic function determinations
• Prostatic acid phosphatase and prostatic specific antigen
• Testosterone, total, serum
For treatment of breast carcinoma
• Alkaline phosphatase, serum values and physical examination and x-rays of known or suspected metastases
• Calcium
For gender change androgen therapy
• LH, ALT [SGPT]

DOSAGE AND ADMINISTRATION:
In general, dosage should be adjusted according to the response of the individual patient. Usually, one injection of 1 ml per two to four weeks is adequate. Sustanon250® should be administered by deep intramuscular injection in gluteal muscle.

Body building: male 500-2000 mg per week, female is not recommended.

HOW SUPPLIED – Sustanon250® Injection, Solution- Intramuscular-250 mg/ml is supplied in multiple dose 10 ml vial with light orange color flip cap.

For shelf-life please refer to the imprint on the pack.

Keep out of reach of children.

Should be at controlled room temperatures 15-30°C (59-86°F)

Do not freeze

This drug should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Warming and shaking the vial should redissolve any crystals that may have formed during storage at temperatures lower than recommended.

Protect from sun light

This drug has not been shown to be safe and effective for the enhancement of athletic performance!

Manufactured and Distributed by: LA Pharma S.r.l.

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