

**SUSTANON**

TESTOSTERONE PROPIONATE BP 30mg  
TESTOSTERONE PHENYLPROPIONATE BP 60mg  
TESTOSTERONE ISOCAPROATE BP 60mg  
TESTOSTERONE DECANOATE BP 100mg  
Oil Base q.s.  
Presented as 10 x 1ml ampoules per box (250mg/ml)

**DESCRIPTION**

Sustanon is used to treat for testosterone replacement therapy in male hypogonadal disorders. It is an oil-based injectable containing four different testosterone esters: testosterone propionate (30 mg); testosterone phenylpropionate (60 mg); testosterone isocaproate (60mg); and testosterone decanoate (100 mg). It is an intelligently “engineered” blend designed to provide fast, yet extended release of testosterone. Thus, it can provide significant gains in strength and muscle tissue, as well as a noticeable increase in libido. The propionate and phenylpropionate esters in this product are quickly utilized, releasing into circulation within the first four days. The remaining esters are much slower to release, staying active in the body for approximately two and three weeks. It has a strong anabolic activity, with a pronounced androgenic component.

SUSTANON is approved for the following uses:

Testosterone replacement therapy In conditions associated with a testosterone deficiency such as:  
Testosterone replacement therapy in male hypogonadal disorders  
Osteoporosis due to androgen deficiency

Testosterone replacement therapy in male hypogonadal disorders, for example:

After castration  
Eunuchoidism  
Hypopituitarism

**ADVERSE REACTIONS**

Endocrine and Urogenital

Female:

The most common side effects of androgen therapy are amenorrhea and other menstrual irregularities, inhibition of gonadotropin secretion, and virilization, including deepening of the voice and clitoral enlargement.

Male:

Gynecomastia, and excessive frequency and duration of penile erections. Oligospermia may occur at high dosages.  
Skin and Appendages : Hirsutism, male pattern baldness and acne.  
Fluid and 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.  
Hematologic : Suppression of cloning factors IL, V, VII, and X; bleeding in-patients on concomitant anti-coagulant therapy.  
Nervous System : Increased or decreased libido, headache, anxiety, depression, and generalized paraesthesia.  
Metabolic : Increased serum cholesterol.  
Miscellaneous : Rarely, anaphylactoid reactions; inflammation and pain at injection site.

**DRUG INTERACTIONS**

When administered concurrently, the following drugs may interact with androgens, such as methandienone, have been reported to decrease the anticoagulant requirement. Patients receiving oral anticoagulant therapy require close monitoring especially when androgens are started or stopped.

Antidiabetic agents, oral or insulin. Cyclosporine Hepatotoxic medications, other human growth hormone (somatrem or somatropin).

**CONTRAINDICATIONS**

Androgens are contraindicated in men with carcinomas of the breast or with known or suspected carcinomas of the prostate and in women who are or may become pregnant.

When administered to pregnant women, androgens cause virilization of the external genitalia of the female fetus. This virilization includes clitoromegaly, abnormal vaginal development, and fusion of genital folds to form a scrotal-like structure. This preparation is also contraindicated in patients with a history of hypersensitivity to any of its components. Patients with a severe heart disease, liver disease and kidney disease.

**PRECAUTIONS**

General: Women should be observed for signs of virilization. Because androgens may alter serum cholesterol concentration, caution should be used when administering these drugs to patients with a history of myocardial infarction or coronary artery disease. All patients: Any nausea, vomiting, changes in skin color or ankle swelling.

**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 : Testosterone replacement therapy in conditions associated with a testosterone deficiency such as: primary hypogonadism, hypogonadotropic hypogonadism, delayed puberty. Treatment of metastatic mammary cancer in women.

**INDICATIONS**

Males

Sustanon Injection is indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone.

Primary hypogonadism : Testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, or orchidectomy.

Hypogonadotropic hypogonadism : Idiopathic gonadotropin or luteinizing hormone – releasing hormone (LHRH) deficiency, or pituitary – hypothalamic injury from tumors, trauma, or radiation.

Delayed Puberty : Testosterone Combo Injection may be used to stimulate puberty in carefully selected males with clearly delayed puberty.

Females

Metastatic mammary cancer: Sustanon Injection may be used secondarily in women with advancing inoperable metastatic mammary cancer who are one to five years postmenopausal. It has also been used in premenopausal women who have benefited from oophorectomy and are considered to have a hormone-responsive tumor.

**CLINICAL PHARMACOLOGY**

Endogenous androgens are responsible for the normal growth and development of the male sex organs and for maintenance of secondary sex characteristics. These effects include growth and maturation of prostate, seminal vesicles, penis and scrotum; development of male hair distribution, such as beard, pubic, chest, and auxiliary hair; laryngeal enlargement; vocal chord thickening; alterations in body musculature; and fat distribution.

Androgens are responsible for the growth spurt of adolescence and for the eventual termination of linear growth, which is brought about by fusion of the epiphyseal growth centers. In children, exogenous androgens accelerate linear growth rates but may cause a disproportionate advancement in bone maturation. Use over long periods may result in fusion of the epiphyseal growth centers and termination of growth process. Androgens have been reported to stimulate the production of red blood cells by enhancing the production of erythropoietic stimulating factor.

FOR PEDIATRICS

Androgens should be used with caution in children and adolescents who are still growing because of possible premature epiphyseal closure in males and females, precocious sexual development in prepubertal males, or virilization in females. Skeletal maturation should be monitored at 6-month intervals by an x-ray of the hand and wrist.

FOR GERIATRICS

Treatment of male patients over the age of approximately 50 years with androgens should be preceded by a thorough examination of the prostate and baseline measurement of prostate specific antigen serum concentration since androgens may cause increased risk of prostatic hypertrophy or may stimulate the growth of occult prostatic carcinoma. Periodic evaluation of prostate function should also be performed during the course of therapy.

**DOSAGE AND ADMINISTRATION**

In males with delayed puberty: Various dosage regimens have been used; some call for lower dosages initially with gradual increases as puberty progresses, with or without a decrease to maintenance levels. Other regimens call for higher dosage to induce pubertal changes and lower dosage for maintenance after puberty. The chronological and skeletal ages must be taken into consideration, both in determining the initial dose and in adjusting the dose. Dosage is within the range of 50 to 200 mg every 2 to 4 weeks for a limited duration, for example, 4 to 6 months. X-rays should be taken at appropriate intervals to determine the amount of bone maturation and skeletal development (see INDICATIONS, USAGE AND WARNINGS).

Palliation of inoperable mammary cancer in woman: A dosage of 200 to 400 mg every 2 to 4 weeks is recommended. Women with metastatic breast carcinoma must be followed closely because androgen therapy occasionally appears to accelerate the disease.

**PRESENTATION**

250 mg/ml, 1 x 10 ml ampoules

**STORAGE**

Store in a cool dry place (< 25 °C).

Protect from light.

Warming and rotating the ampoule between the palms of the hands will redissolve any crystals that may have been formed during storage at low temperatures