MMALABS®

Muscular Modification Assistance LABS®

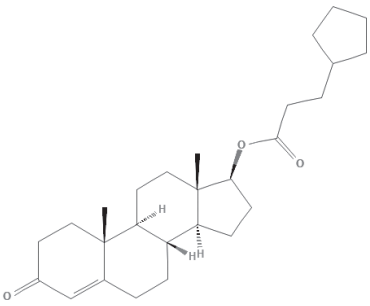
TESTOSTERONE CYPIONATE 250mg/ml

Testosterone Cypionate 250mg/ml

Molecular Formula:
C27H4003

Molecular Weight:
412.61

Structure:



DESCRIPTION

Testosterone Cypionate 250 Injection provides testosterone cypionate, a derivative of the primary endogenous androgen testosterone.

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 auxillary 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 erythropoeitic stimulating factor. During exogenous administration of androgens,Â endogenous testosteroneÂ release is inhibited through feedback inhibition of pituitary luteinizing hormone (LH).

ADVERSE REACTIONS

Endocrine and Urogenital, Female: The most common side effects of androgen therapy are amenorrhea and other menstrual irregularities, inihibition 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 concominant anti-coagulant therapy.

Nervous System : Increased or decreased libido, headache, anxiety, depression, and generalized paresthesia.

Metabolic : Increased serum cholesterol. Miscellaneous : Rarely, anaphylactoid reactions; inflammation and pain at injection site.

INDICATIONS

Males: Testosterone Cypionate 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 Cypionate Injection may be used to stimulate puberty in carefully selected males with clearly delayed puberty.

Females: Metastatic mammary cancer: Testosterone Cypionate 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.

DRUG INTERACTIONS

When administered concurrently, the following drugs may interact with androgens, such as methandrostenolone, have been reported to decrease the antocoagulant 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

For gender change androgen therapy:

LH (Luteinizing hormone)
ALT [SGPT] (Alkaline aminotransferase)

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 prostatespecific 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 AND 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 occassionally appears to accelerate the disease.

PACKAGING

100 mg/ml, 1 ml cartridges

STORAGE

Store in a cool dry place (< 25 ºC). Protect from light. Warming and rotating the vial between the palms of the hands will redissolve any crystals that may have been formed during storage at low temperatures.

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