MMALABS®

Muscular Modification Assistance LABS®

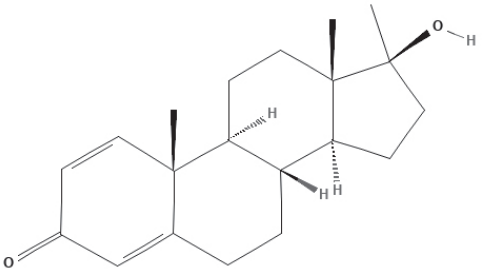
TESTOSTERONE PROPIONATE 100mg/ml

Testosterone Propionate100mg/ml

Molecular Formula:
C22H32O3

Molecular Weight:
344.495 g/mol

Structure:



DESCRIPTION

Testosterone Propionate (injection, USP) provides testosterone propionate, an esterified derivative of the primary endogenous androgen testosterone for intramuscular use. In bioactive form, androgens have a 17-beta-hydroxy group, the esterification of which produces esters of testosterone which undergo hydrolysis in vivo; producing a delayed release of the bioactive testosterone. Each ml of Testosterone Propionate contains 100mg of testosterone propionate in ethyl oleate (base oil).

CLINICAL PHARMACOLOGY

Endogenous androgens such as testosterone are responsible for the development and growth of the male sexual organs and post-adolescent secondary sex characteristics. Androgen effects include but are not limited to the maturation of the penis, scrotum, prostate, seminal tubules, laryngeal enlargement, vocal cord thickening, changes in muscle mass and fat distribution, and the development and distribution of male hair (facial, pubic, chest, back, axillary).

Androgens have been linked to increased protein anabolism and consequent decreased protein catabolism.

Androgens increase retention of sodium, potassium, and phosphorus. Androgens decrease urinary excretion of calcium.

Androgens are responsible for the growth spurt of adolescence and the aromatization of androgens to estrogens 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 the growth process. Androgens have been reported to stimulate the production of red blood cells by enhancing the production of erythropoietin stimulating factor.

Androgens may suppress gonadotrophic function of the pituitary. During exogenous administration of androgens, endogenous testosterone release is inhibited through feedback inhibition of pituitary luteinizing hormone (LH). With large doses, spermatogenesis may be suppressed through feedback inhibition of pituitary follicle stimulating hormone (FSH).

INDICATION AND USAGE

Males: Androgen Replacement Therapy:
-Testosterone Propionate is indicated for androgen replacement therapy in conditions associated with deficiency or absence of endogenous testosterone.
-Primary hypogonadism: Testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, or orchiectomy.
-Hypogonadotropic hypogonadism: Idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation.
- Delayed puberty: Testosterone Propionate Injection may be used to stimulate puberty in carefully selected males with clearly delayed puberty that is not secondary to other pathological disorders.

Females: Metastatic mammary cancer: Testosterone Propionate Injection may be used secondarily in women with advancing inoperable metastatic mammary cancer who are one to five years post-menopausal. It has also been used in pre-menopausal women with breast cancer who have benefited from oophorectomy and are considered to have a hormone-responsive tumor.

-Postpartum Breast Engorgement: as recommended by qualified physician.

CONTRAINDICATIONS
1. Diagnosed or suspected carcinoma of the male breast or prostate.
2. Women who are pregnant or may become pregnant because of possible masculinization of the fetus. 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.
3. Patients with a history of hypersensitivity to Test-Prop or any of its components.
4. Patients with serious renal, cardiac, or hepatic dysfunction.

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.

SIDE EFFECTS
-Males: Frequent or persistent penile erections and increases in the appearance of acne vulgaris.
-Females: Hoarseness of the voice, acne, changes in menstrual periods, or more facial hair.
-All patients: Nausea, vomiting, changes in skin color, or ankle swelling.

DRUG INTERACTIONS
Anti-diabetic drugs and Insulin: In diabetic patients, the metabolic effects of androgens may reduce blood glucose, insulin, and anti-diabetic medication requirements.
Adrenal steroids or ACTH: May exacerbate edema in patients on concurrent adrenal-cortical steroids or ACTH therapy.
Anticoagulants: Patients on anticoagulants such as warfarin should be carefully monitored during androgen therapy as androgens may increase sensitivity to oral anticoagulants which may require a concomitant reduction in anticoagulant dosage to achieve a desirable prothrombin time (PT). Concurrent use of anti-diabetic agents, insulin, cyclosporines, hepatotoxic medications, and/or human growth hormone (somatropin) has been reported to decrease anticoagulant requirements. Anticoagulant patients should be monitored regularly during androgen therapy, particularly during initiation and termination of therapy.
Oxyphenbutazone: Elevated serum levels of oxyphenbutazone may result.

DOSAGE AND ADMINISTRATION
Male Androgen Replacement Therapy: Generally 25 to 50 mg injected intramuscularly (IM) 2 to 3 times per week. Titrate to desired serum levels.

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 change in maintenance levels. Other regimens call for higher dosages to induce pubertal changes and lower dosages 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 generally within the lower ranges and only 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 WARNINGS).

Palliation of Mammary Cancer in Women: Generally a dosage of 50 to 100 mg is administered intramuscularly (IM) 3 times per week. Some physicians prefer short acting testosterone esters for treatment of breast carcinoma during the initiation of therapy for ease of titration and to better assess patient tolerance of the medication. Women with metastatic breast carcinoma must be followed closely because androgen therapy has been reported in rare instances to accelerate the disease.

PACKAGING
100 mg/ml, 1 ml cartridges

STORAGE
Store in a cool dry place (30 C± 2 C). Protect from light. Warming and rotating the vial between the palms of the hands will redissolve any crystals that may have formed during storage at low temperatures.

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