



MMALABS®

Muscular Modification Assistance LABS®

DROSTANOLONE PROPIONATE 100mg/ml

Drostanolone Propionate 100mg/ml

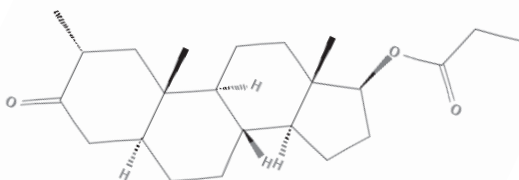
Molecular Formula:

C₂₃H₃₆O₃

Molecular Weight:

360.538 g/mol

Structure:



DESCRIPTION

Drostanolone Propionate is a man-made steroid, similar to the naturally occurring steroid testosterone.

CLINICAL PHARMACOLOGY

Endogenous androgens such as testosterone or derivatives 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:

Drostanolone Propionate is used to promote weight gain following extensive surgery, chronic infection, or severe trauma, and in other cases that result in inadequate weight gain or maintenance. Drostanolone Propionate is also used to decrease muscle loss caused by treatment with corticosteroids and to reduce bone pain associated with osteoporosis.

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 Drostanolone Propionate or any of its components.
4. Patients with serious renal, cardiac, or hepatic dysfunction.

WARNINGS

1. In breast cancer patients, androgen therapy may cause hypercalcemia through stimulated osteolysis. Frequent monitoring of urine and serum calcium is indicated in such patients. If hypercalcemia presents, the androgen should be discontinued.
2. Prolonged usage of high doses of androgens has been associated with peliosis hepatis, hepatic neoplasms, and hepatocellular carcinoma as well as azoospermia, oligospermia, and reduced ejaculatory volume.

3. If liver function tests become abnormal or the patient presents with cholestatic hepatitis with jaundice, androgen therapy should be discontinued pending determination of the etiology.

4. Edema due to sodium and water retention may be a serious complication in patients with pre-existing cardiac, renal, or hepatic disease, migraines, epilepsy, and other conditions. Edema may be increased in patients on concurrent adrenal cortical steroid or ACTH therapy.

5. Liver cell tumors have also been reported, most often benign and androgen-dependent, although fatal malignant tumors have also been reported. Termination of the drug generally results in regression or the cessation of tumor progression.

6. Geriatric patients receiving androgen therapy may be at increased risk for prostate hypertrophy and prostatic carcinoma.

7. Virilization of female patients may occur. If signs of virilization present during treatment of breast carcinoma, androgen therapy should be discontinued.

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.

Laboratory Tests and Patient Monitoring:

Examination of bone age by x-ray should be conducted during treatment of children to determine bone maturation rate and effect on epiphyseal centers.

Women with breast carcinoma should have frequent assays of serum and urine calcium throughout the course of treatment.

Androgens have been associated with increases in low-density lipoproteins and reduction in high-density lipoproteins in serum. Periodic serum lipid assays are recommended during treatment.

Serum assays for hematocrit and hemoglobin are recommended to screen for polycythemia in patients receiving large doses of androgens.

Hepatic function determinations should be made periodically including at a minimum AST and ALT, particularly with concomitant use of hepatotoxic medications or with a history of liver disease.

Androgen therapy patients, particularly those over 50 years of age, should be evaluated periodically for prostatic acid phosphatase and prostate specific antigen (PSA) total and free.

Total testosterone, free testosterone, and bioavailable testosterone in serum should be assayed periodically and dosing titrated as necessary to achieve desired levels.

For treatment of breast carcinoma:

Alkaline phosphatase serum values, physical examination, and x-rays of known or suspected metastases.

Calcium

For gender change androgen therapy:

- LH (Luteinizing Hormone)

- ALT (Alkaline aminotransferase)

Thyroid Testing Interaction: Androgens have been shown to reduce concentration of thyroxine-binding globulin and consequently decreasing the total serum T4 and increasing uptake of both T3 and T4. Serum concentration of free (unbound) thyroid hormones will not change.

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: The dose of these medicines will be different for different patients. Follow your doctor's orders or the directions on the label. The following information includes only the average doses of these medicines. If your dose is different, do not change it unless your doctor tells you to do so.

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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