

DROSTANOLONE PROPIONATE

DROSTANOLONE PROPIONATE USP 100mg Oil Base q.s.

Presented as box with 10 ml vial (multidose)

DESCRIPTION

DROSTANOLONE PROPIONATE is a man-made steroid, similar to the naturally occurring steroid testosterone.

INDICATIONS

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.

DOSAGE AND DIRECTIONS FOR USE

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.

SIDE EFFECTS AND SPECIAL PRECAUTIONS

GI/Hepatic: Nausea, peliosis hepatis, cholestatic jaundice, and very rarely hepatic necrosis. Hepatocellular neoplasms after long term use; May affect liver function tests.

CNS: Changes in libido, headache, habituation, excitation, generalized paresthesia, insomnia, anxiety and depression.

Hematological: Suppression of clotting factors II, V, VII, and X. Bleeding on con- comitant anticoagulant therapy. Polycythemia.

Breast: Gynecomastia.

Larynx: Deepening of the voice in females.

Fluids and Electrolytes: Retention of electrolytes including sodium, potassium, chlorine, water, calcium, and inorganic phosphates.

Skeletal: Premature closure of epiphyses in children.

Other: Rarely, anaphylactoid reactions; inflammation or pain at the injection site.

In males: Excessive frequency, duration, and persistence of penile erections.

In females: Virilization including clitoral enlargement, menstrual irregularities, amenorrhea, inhibition of gonadotrophin secretion, and deepening of the voice. In pregnant women, virilization of external genitalia of the female fetus.

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.

PRESENTATION

100 mg/ml, 1 x 10 ml vial

STORAGE

Store in a cool dry place (30 °C E 2 °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