

**Testosterone Enanthate 350mg/ml**

**1 VIAL containing 10 mL**

**For multidose use**

**Therapeutic Class:**

Anabolic Agent

**Composition:**

Each 1 ml of ENANTREX350 contains:

- 350 mg Testosterone Enanthate
- Ethyl Oleate q.s.

**Indication & Dosage:**

**Intramuscular**

**Male hypogonadism**

Adult: 50-400 mg every 2-4 wk for the cypionate;

50-400 mg every 2-4 wk for the enanthate (or an initial

dose of 250 mg every 2-3 wk followed by a maintenance

dose every 3-6 wk);

up to 50 mg 2-3 times wkl for the propionate.

**Inoperable metastatic breast cancer**

Adult: As enanthate: 200-400 mg every 2-4 wk.

**Contraindications:**

Hypercalcaemia or hypercalciuria, males with breast or prostate carcinoma.

Pregnancy and lactation.

**Special Precautions**

Cardiovascular disorders, skeletal metastases, renal or hepatic impairment, epilepsy, migraine, diabetes or other conditions which may be aggravated by fluid retention, eg heart failure. Elderly, prepubertal boys. Monitor signs of virilization (females) and development of priapism or excessive sexual stimulation (males). Periodic haemoglobin, lipid determinations and rectal prostate examination.

**Adverse Drug Reactions**

Fluid and electrolyte retention; increased vascularity of the skin; hypercalcaemia, impaired glucose tolerance; increased bone growth and skeletal weight; increase LDL cholesterol; increase haematocrit and fibrinolytic activity; headache, depression and GI bleeding.

**Males:** spermatogenesis suppression, priapism, gynaecomastia,

prostatic hyperplasia and accelerate growth of malignant prostate neoplasms.

**Females:** suppression of lactation, ovarian activity and menstruation; virilization, clitoris hypertrophy, increased libido, oily skin, acne, hirsutism, male pattern baldness.

**Children:** Closure of the epiphyses and stop linear growth in early puberty, symptoms of virilisation. Precocious sexual development, increased frequency of erection in boys, and clitoral enlargement in girls. IM: urticaria, inflammation at Inj site, postinjection induration, furunculosis

**Potentially Fatal:** Peliosis hepatis, liver toxicity, malignant neoplasm.

**Drug Interactions**

Enhance activities of ciclosporine, antidiabetics, thyroxine, anticoagulants. Long term use of testosterone may cause resistance to effects of neuromuscular blockers. Enhance fluid retention from corticosteroids.

**Lab Interference**

May decrease protein bound iodine (PBI) and thyroxine-binding globulin concentrations. May cause a decrease in excretion of creatinine and creatine and increase in excretion of 17-ketosteroids.

**Pregnancy Category**

Category X: Studies in animals or human beings have demonstrated foetal abnormalities or there is evidence of foetal risk based on human experience or both, and the risk of the use of the drug in pregnant women clearly outweighs any possible benefit. The drug is contraindicated in women who are or may become pregnant.

**Mechanism of Action**

Testosterone is the principal endogenous androgen responsible for promoting the growth and development of male sexual organs and maintaining secondary sex characteristics in androgen-deficient males.

**Absorption:** Absorbed from GI tract, skin, and oral mucosa

**Distribution:** 80% bound to sex-hormone binding globulin.

Undergo enterohepatic recirculation.

**Half-life of testosterone:** 10 to 100 min.

**Metabolism:** Hepatic to active and inactive metabolites.

**Excretion:** Excreted via urine as metabolites; and faeces

as unchanged drug (6%)

**CIMS Class :** Androgens & Related Synthetic Drugs

**ATC Classification:** G03BA03 - testosterone ; Belongs to

the class of 3-oxoandrosten (4) derivative androgens used

in androgenic hormone preparations.

**Storage:**

Store at room temperature, between 59 and 86 degrees F (15 and 30 degrees C), in a tightly-closed container. Store away from heat, moisture, and light.

Do not store in the bathroom. Keep out of the reach of children and away from pets.

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Manufactured under WHO cGMP guidelines

www.concentrexlabs.com

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