

Testobolin® 250mg/ml

GENERIC NAME

Testosterone Enanthate

CHEMICAL NAME

17β-[(1-Oxoheptyl) Oxy] Androst-4-en-3-on

MOLECULAR STRUCTURE

C₂₆H₄₀O₃

MOLECULAR WEIGHT

400.6

PROPRIETARY NAME: Testobolin®

DOSAGE FORM: 250mg/ml injection

COMPOSITION

Each ml of Testobolin contains Testosterone Enanthate USP 250mg in oily base quantity sufficient.

PHARMACOLOGICAL CLASSIFICATION

Androgenic Hormone.

MECHANISM OF ACTION

Testosterone is secreted by the interstitial leydig cell of the testes under the influence of LH from pituitary. FSH is mainly responsible for promotion of spermatogenesis in tubular cells. Testosterone is responsible for all the changes that occur in a body at puberty. It is needed for normal spermatogenesis and maturation of spermatozoa and promotes muscle building specially if aided by exercise.

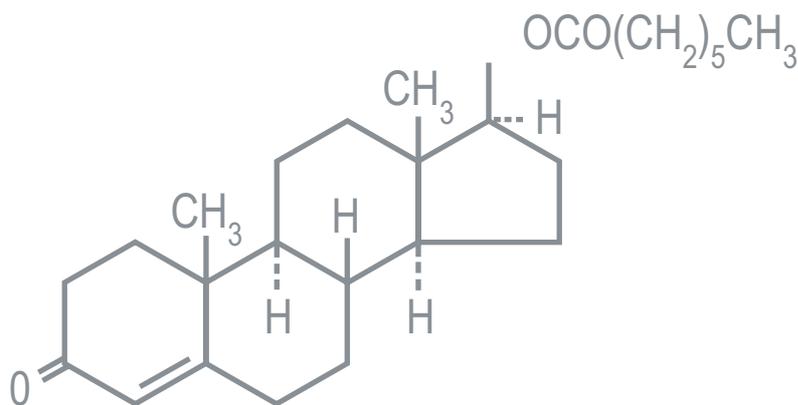
PHARMACOKINETIC PROPERTIES

Testosterone enanthate esters are less polar than free testosterone. Testosterone enanthate esters in oil administered intramuscularly are absorbed slowly from the lipid phase, thus testosterone enanthate can be given at intervals of two to four weeks. Testosterone in plasma is 98% bound to a specific testosterone-estradiol binding globulin, and approximately 2% is free.

About 90% of a dose of testosterone is excreted in the urine as glucuronic and sulfuric acid conjugates of testosterone and its metabolites; 6% of a dose is excreted in the feces, mostly in unconjugated form. Inactivation of testosterone occurs primarily in the liver. Testosterone is metabolized to various 17-keto steroids through two different pathways. In responsive tissues, the activity of testosterone appears to depend on reduction to dihydrotestosterone, which binds to cytosol receptor proteins. The steroid-receptor complex is transported to the nucleus where it initiates transcription events and cellular changes.



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INDICATIONS

MALE:

- I. Testobolin is indicated for replacement therapy in the treatment of hypogonadism associated with anaemia and androgenic deficiency with testicular failure, accidental castration.
- II. In hereditary angioneurotic oedema, infertility due to defective spermatogenesis, osteoporosis, refractory anemia, and endometriosis.
- III. To improve nitrogen balance in catabolic state. Certain types of infertility due to disorders of spermatogenesis.

FEMALE:

- I. Supplementary therapy in disseminated breast carcinoma in the post menopausal period.

ADVERSE REACTIONS

FEMALE:

Amenorrhea, menstrual irregularities, virilization including deepening of voice and clitoral enlargement.

MALE:

Gynaecomastia, oligospermia at higher doses (reduction in spermatogenesis) and excessive frequency and duration of penile erection. Hirsutism, acne and male pattern baldness

Fluid and electrolyte disturbances – Retention of water, sodium, calcium, potassium. Chloride and inorganic phosphates. Nausea, cholestatic jaundice, alterations in liver function, polycythemia, acne, precocious puberty, premature epiphyseal closure, increased or decreased libido, headache, anxiety and depression.

CONTRAINDICATIONS

Contraindicated in prostate and male breast carcinoma and liver and kidney dysfunction. Testobolin® should not be used in patients with known hypersensitivity to testosterone or any of its excipients.

Contraindicated in infant, pregnancy, lactating mothers as testosterone supplements cause foetal harm.



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WARNINGS

In patients with breast carcinoma, hormonal therapy may cause hypercalcemia, the drug should be discontinued and appropriate measures should be taken. The androgen therapy should be discontinued and the etiology should be determined, if cholestatic hepatitis with jaundice appears or if liver function tests become abnormal. Due to oedema, with or without congestive heart failure may be a serious complication in patients with preexisting cardiac, renal, or hepatic disease. In addition to discontinuation of the drug, diuretic therapy may be required. If the administration of testosterone enanthate is restarted, a lower dose should be considered. Gynaecomastia frequently develops and occasionally persists in patients being treated for hypogonadism.

SPECIAL PRECAUTIONS

The use of testosterone in women may cause symptoms of virilization such as acne vulgaris which manifests itself on the back, chest, shoulders, and arms more than on the face. Caution should be taken when administering testosterone enanthate to patients with a history of myocardial infarction or coronary artery disease as androgens may alter serum cholesterol concentrations.

DRUG INTERACTIONS

Enhances effect of oral anticoagulant, corticosteroid and oral hypoglycemics . Enzyme inducer like rifampicin and phenobarbitone may increase rate of its metabolism. Testobolin when administered concurrently with Oxyphenbutazone, that elevates serum level.

PRESENTATION

5 ampoules of 1ml (250mg/ml) in 2 plastic tray and such 2 trays in a carton.

DOSAGE AND DIRECTIONS FOR USE

Testobolin® injections are only to be administered intramuscularly.

MALES:

Hypogonadism: Intramuscular administration of 50 to 400 mg every 2 to 4 weeks as replacement therapy i.e., eunuchism.



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FEMALE:

Intramuscular administration of 200 to 400 mg every 2 to 4 weeks is recommended as supplementary therapy in disseminated breast carcinoma in post menopausal period. Women with metastatic breast carcinoma must be followed closely because androgen therapy occasionally appears to accelerate the disease.

STORAGE:

Store in a cool dry place below 25° C (77 °F).

Ampoules to be stored in outer carton box.

MARKETED BY

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