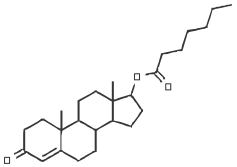
Testosterone Enanthate USP

For Intramuscular Use

CHEMICAL NAME
androst-4-en-3-one, 17-[(1-oxoheptyl)oxy]-, (17β)-

MOLECULAR STRUCTURE
C26H40O3



MOLECULAR MASS
400.6

COMPOSITION
Each mL contains:

Testosterone enanthate USP	250 mg
Benzyl alcohol USP	15% v/v
Oil base	q.s.

PHARMACOLOGICAL CLASSIFICATION
Anabolic steroid

MECHANISM OF ACTION
It is secreted by the interstitial (Leydig) cells of the testes under the influence of pituitary LH. FSH is primarily responsible for promoting spermatogenesis in the tubular cells. Testosterone is responsible for all the changes that occur in the body during puberty. It is necessary for normal spermatogenesis and sperm maturation and promotes muscle building, especially when aided by exercise.

PHARMACOKINETIC PROPERTIES
Testosterone enanthate esters are less polar than free testosterone. Testosterone esters in oil administered intramuscularly are slowly absorbed from the lipid phase; thus, testosterone enanthate can be administered at intervals of two to four weeks. In plasma, 98% of testosterone is bound to a specific testosterone-estradiol-binding globulin, and approximately 2% is free. Approximately 90% of a testosterone dose 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, mainly in unconjugated form. Testosterone inactivation occurs primarily in the liver. In responsive tissues, testosterone activity appears to depend on its reduction to dihydrotestosterone, which binds to cytosolic receptor proteins.

INDICATIONS

MEN:

Treatment of hypogonadism resulting from androgen deficiency and anemia. Replacement therapy to maintain sexual characteristics in adults with

testicular insufficiency or following accidental castration. • Hereditary angioneurotic edema,

infertility due to defective spermatogenesis, osteoporosis, refractory anemia, and endometriosis. • To improve nitrogen balance in catabolic states.

Certain types of infertility due to spermatogenesis disorders.

WOMEN:

• Supplementary therapy for disseminated breast carcinoma in the postmenopausal period.

ADVERSE REACTIONS
WOMEN:
Amenorrhea, menstrual irregularities, virilization (including deepening of the voice and clitoral enlargement).
MEN:
Gynecomastia, oligospermia at higher doses (i.e., reduced spermatogenesis), and excessive frequency and duration of penile erections.
GENERAL:
Fluid and electrolyte disturbances – retention of water, sodium, calcium, potassium, chloride, and inorganic phosphates. Nausea, cholestatic jaundice, altered liver function, acne, polycythemia, precocious puberty, premature epiphyseal closure, increased or decreased libido, headache, anxiety, and depression.

CONTRAINDICATIONS
Contraindicated in cases of prostate carcinoma, male breast carcinoma, and hepatic or renal dysfunction. Testosterone must not be used in patients with known hypersensitivity to testosterone or any of its excipients. Contraindicated during pregnancy and in nursing mothers, as testosterone supplementation causes fetal harm.

WARNINGS
In patients with breast carcinoma, hormonal therapy may cause hypercalcemia; the drug should be discontinued and appropriate measures taken. If cholestatic hepatitis with jaundice occurs, or if liver function tests become abnormal, the androgen should be discontinued and the etiology determined. Drug-induced jaundice is reversible upon discontinuation of the drug. Geriatric patients treated with androgens may be at increased risk of developing prostatic hypertrophy and prostatic carcinoma. Due to sodium and water retention, edema—with or without congestive heart failure—may be a serious complication in patients with pre-existing cardiac, renal, or hepatic disease. Increased water retention may manifest as swelling. In addition to discontinuing the drug, diuretic therapy may be required. If administration of testosterone enanthate is resumed, a lower dose should be considered. Gynecomastia frequently develops and occasionally persists in patients undergoing treatment for hypogonadism.

SPECIAL PRECAUTIONS
Women should generally avoid the use of androgens, as this may result in unpleasant androgen-related side effects. The use of testosterone in women can cause symptoms of virilization, such as acne vulgaris; many women experience severe acne vulgaris with testosterone enanthate, manifesting on the back, chest, shoulders, and arms rather than the face. Caution should be exercised when administering testosterone to patients with a history of myocardial infarction or coronary artery disease, as androgens may alter serum cholesterol concentrations.

DRUG INTERACTIONS
Concomitant administration with the following drugs demonstrates interaction with androgens—oral hypoglycemic agents and insulin: the metabolic effects of androgens may reduce blood glucose and insulin levels in diabetic patients. Corticosteroids: increased tendency for edema; use with caution in patients with liver or heart disease. Oxyphenbutazone: may result in elevated serum levels of oxyphenbutazone. Enzyme-inducing agents may increase or decrease testosterone levels; therefore, adjustment of the dosage and/or injection intervals may be required.

EFFECTS ON THE ABILITY TO DRIVE AND USE MACHINES:
No studies suggest an influence on alertness and concentration.

OVERDOSE
The acute intramuscular toxicity of testosterone is very low. Priapism in men is a symptom of chronic overdose. If this occurs, testosterone treatment should be discontinued and, once the symptom resolves, restarted at a lower dose.

DOSAGE AND ADMINISTRATION
Testosterone injections must be administered only via the intramuscular route. MEN: Hypogonadism: intramuscular administration of 50 to 400 mg every 2 to 4 weeks as replacement therapy (e.g., for eunuchism). WOMEN: Intramuscular administration of 200 to 400 mg every 2 to 4 weeks is recommended as adjunctive therapy for disseminated breast carcinoma in postmenopausal women. Women with metastatic breast carcinoma should be closely monitored, as androgen therapy occasionally appears to accelerate the disease.

STORAGE:
Store below 25°C. Do not freeze.

Keep out of the reach of children.

Presentation
5 x 1 mL ampoules

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