Testosterone Cypionate Injection, USP

Rx ONLY

DESCRIPTION
Testosterone cypionate, for intramuscular injection, contains testosterone cypionate which is the oil-soluble 17 (β)-cyclopentylpropionate ester of the androgenic hormone testosterone. Testosterone cypionate is a white or creamy white crystalline powder, odorless or nearly so and stable at air. It is insoluble in water, freely soluble in alcohol, chloroform, dioxane, ether, and soluble in vegetable oils.

The chemical name for testosterone cypionate is androst-4-en-3-one, 17-(3-cyclopentyl-1-oxopropoxy)-, (17β)-. Its molecular formula is C27H40O3, and the molecular weight is 444.61.

The structural formula is represented below:

\[ \text{C}_{27}\text{H}_{40}\text{O}_3 \]

Testosterone cypionate is available in one strength, 200 mg/mL, testosterone cypionate. Each mL of solution contains Testosterone Cypionate, 200 mg; Benzyl Benzoate, 0.2 mL; Cottonseed Oil, 460 mL; 560 mg Benzyl Alcohol (as preservative), 9.45 mg.

CLINICAL PHARMACOLOGY
Endogenous androgens are responsible for normal growth and development of the male sex organs and for maintenance of secondary sex characteristics. These effects include growth and maturation of the prostate, seminal vesicles, penis, and scrotum; development of male hair distribution, such as beard, pubic, axillary, and程matory chest hair; larynx enlargement, vocal cord thickening, and alteration of body musculature and fat distribution. Drugs in this class also cause retention of nitrogen, sodium, potassium, and phosphorus, and decreased urinary excretion of calcium.

Anabolic effects of testosterone may cause some degree of water and sodium retention. This may be more likely to develop in edematous individuals, e.g., those with cardiac or hepatic disease or with marked hypoproteinemia (e.g., nephrotic syndrome).

Androgen therapy should be used cautiously in healthy males with delayed puberty. The effect on infants may be more likely to develop toxicity.

Androgens are responsible for the growth spurt of adolescence and for eventual termination of linear growth. Bone maturation should be monitored by assessing bone age of the wrist and hand every 6 months. The use of androgens, in general, should be limited, and the dosage adjusted so that the patient receives the minimum amount necessary to achieve the desired therapeutic effect. These conditions must be monitored by the patient’s prescriber.

Androgen therapy may lead to a reduction in high-density lipoprotein (HDL) cholesterol. The degree of this response has not been studied in controlled trials, and does not appear to be dose related.

During exogenous administration of androgens, endogenous testosterone is inhibited through feedback inhibition of pituitary luteinizing hormone (LH) and follicle stimulating hormone (FSH). At large doses of exogenous androgens, spermatogenesis may also be suppressed through feedback inhibition of pituitary follicle stimulating hormone (FSH).

Indications
Testosterone cypionate injection is indicated for replacement therapy in male patients with age-related hypogonadism (also referred to as "late-onset hypogonadism") who have not been established.

Safety and efficacy of testosterone cypionate in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.

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CONTRAINDICATIONS
1. Known hypersensitivity to the drug
2. Males with carcinoma of the breast
3. Males with known or suspected carcinoma of the prostate gland
4. Women who are or who may become pregnant
5. Patients with serious cardiac, hepatic or renal disease

INDICATIONS AND USAGE
Testosterone cypionate injection is intended for replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone.

Testosterone is metabolized to various 17-keto steroids through two different pathways. The half-life of testosterone cypionate when injected intramuscularly is approximately eight days. The total body clearance of testosterone is unaffected by age, but its elimination is reduced by liver disease. The total body clearance of testosterone cypionate is similar to that of testosterone itself.

Long term clinical safety trials have not been conducted to assess the cardiovascular outcomes associated with development of hepatic adenomas, hepatocellular carcinoma, and peliosis hepatis (or "cottonseed oil disease") has been reported in association with the "gasping syndrome", the minimum amount of benzyl alcohol at which toxicity may occur is not known. The risk of benzyl alcohol toxicity depends on the quantity administered and the hepatic capacity to detoxify the chemical. Premature and low-birth weight infants are particularly susceptible to benzyl alcohol toxicity, which can result in death due to respiratory depression.

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There is a lack of substantial evidence that androgens are effective in fractures, surgery, convalescence, and urinary function in elderly patients.

Pharmacokinetics
Testosterone esters are less polar than free testosterone. Testosterone esters in oil injected intramuscularly are absorbed slowly from the lipid phase; thus, testosterone cypionate can be injected at intervals of two to four weeks.

Testosterone in plasma is 98 percent bound to a specific testosterone–estradiol binding globulin, and about 2 percent is free. Generally, the amount of this sex-hormone binding globulin in the plasma will determine the distribution of testosterone between free and bound forms, and the free testosterone concentration will determine its half-life.

During exogenous administration of androgens, endogenous testosterone is inhibited through feedback inhibition of pituitary luteinizing hormone (LH) and follicle stimulating hormone (FSH). The degree of this response has not been studied in controlled trials, and does not appear to be dose related.

The half-life of testosterone cypionate when injected intramuscularly is approximately eight days. In many 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 related to androgen action.

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In children, androgen treatment may become bone maturation without producing compensatory gain in linear growth. This adverse effect may result in compromised adult stature. The younger the child the greater the risk of compromising final mature height.

This drug has not been shown to be safe and effective for the enhancement of athletic performance. Because of the potential risk of serious adverse health effects, this drug should not be used for such purpose.

PRECAUTIONS

General: Use with caution in benign prostatic hypertrophy may develop acute urinary obstruction. Prostate or excessive sexual stimulation may develop. Orchiectomy may occur after prolonged administration or excessive dosage. If any of these effects appear, the androgen should be discontinued, and if restarted, should be at a lower dosage.

Testosterone oxypamine should not be used interchangeably with testosterone propionate because of differences in duration of action.

Information for patients: Patients should be instructed to report any of the following: nausea, vomiting, changes in skin color, ankle swelling, too frequent or persistent erections of the penis.

Testosterone cypionate is not recommended for use in nursing mothers.

Pediatric use: Safety and effectiveness in pediatric patients below the age of 12 years has not been established.

REVERSE ADVERSE

The food and Drug Administration has received reports in the male have occurred with androgens: Endocrine and urogenital: Gynecomastia and excessive frequency and duration of penile erections. Oligospermia may occur at high dosages.

Cardiovascular: Myocardial infarction, stroke.

Gastrointestinal: Nausea, cholestatic jaundice, alterations in liver function tests, rarely hepatocellular neoplasms and peliosis hepatis (see WARNINGS).


Nervous system: Increased or decreased libido, headache, anxiety, depression, and generalized paresthesia.

Miscellaneous: Hypersensitivity, including skin manifestations and anaphylactoid reactions. Vascular Disorders: Venous thromboembolism.

ADVERSE REACTIONS

To report SUSPECTED ADVERSE REACTIONS, contact Perrigo at 1-866-634-9120 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DOSAGE AND ADMINISTRATION

Prior to initiating testosterone cypionate, confirm the diagnosis of hypogonadism by ensuring that serum testosterone concentrations are lower than recommended. Serum testosterone concentrations should be redissolved any crystals that may have formed during storage at temperatures prior to administration, whenever solution and container permit. Warming and shaking the vial should redissolve any crystals that may have formed during storage at temperatures lower than recommended.

HOW SUPPLIED

Testosterone Cypionate Injection, USP, 200 mg/mL is available as follows:

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Vials should be stored at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from light. Use carton to protect contents from light until used.

Manufactured By
PharmaForce, Inc.
Hilliard, OH 43026

PHARMACOTHERAPEUTIC CLASS:
Anabolic Agent

DRUG ABUSE AND DEPENDENCE

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Warming and shaking the vial should redissolve any crystals that may have formed during storage at temperatures lower than recommended.

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