

Cypobolin® 250mg/ml



GENERIC NAME

Testosterone Cypionate

CHEMICAL NAME

Androst-4-en-3-one, 17-(3-cyclopentyl-1-oxopropoxy)-, (17β)-

Alpha · Pharma
healthcare

MOLECULAR STRUCTURE

C₂₇H₄₀O₃

MOLECULAR WEIGHT

412.6112

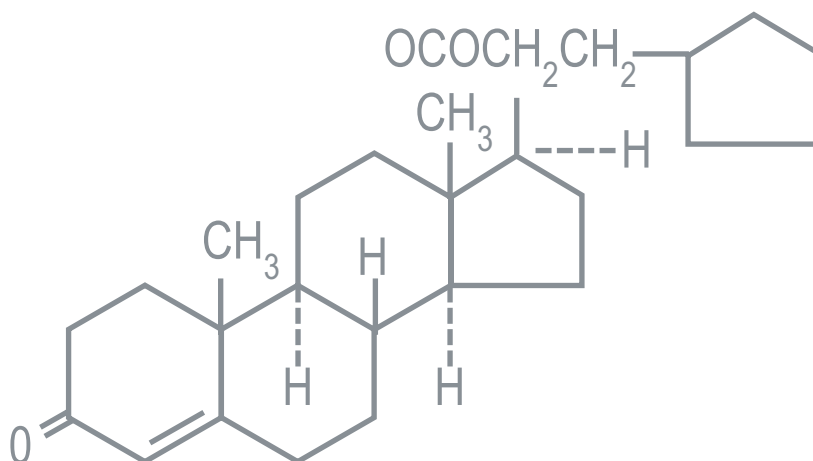
DOSAGE FORM: 250 mg/ml injection

COMPOSITION

Each ml of the solution contains:

Testosterone Cypionate USP.....250 mg

Ethyl Oleate N.FQ S



PHARMACOLOGICAL CLASSIFICATION

Cypobolin® is a steroid hormone from the androgen group, which contains Testosterone Cypionate. Testosterone is primarily secreted in the testes of males and the ovaries of females although small amounts are secreted by the adrenal glands. It is the principal male sex hormone and an anabolic steroid.

PHARMACOKINETICS

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

The half-life of Testosterone Cypionate when injected intramuscularly is approximately eight days.

INDICATIONS AND USAGE

Cypobolin® is indicated for replacement therapy in male in conditions associated with symptoms of deficiency or absence of endogenous testosterone.

1. Primary hypogonadism (congenital or acquired)-testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome; or orchidectomy.
2. Hypogonadotropic hypogonadism (congenital or acquired)-idiopathic gonadotropin or LHRH deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation.

DOSAGE AND ADMINISTRATION

Cypobolin® injection is for intramuscular use only. Intramuscular injections should be given deep in the gluteal muscle.

Cypobolin® is injected between once every week to once every three weeks. The dosage for Cypobolin® varies depending on the age, sex, and diagnosis of the individual patient. The dosage

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$C_{27}H_{40}O_3$

DOSAGE AND ADMINISTRATION (Contd.)

and cycle should be decided in consultation with a physician. Short cycles (6-8 weeks) are often the most beneficial, in order to minimize potential side effects and maximize potential benefit.

SIDE EFFECTS

Allergic reaction, difficulty breathing, swelling of face, lips, tongue, or throat, rapid weight gain, gynecomastia are observed.

The most common side effects in both men and women include increased facial and body hair, oily skin or acne, male pattern baldness, water retention, joint stiffness and soreness at the injection site. A deepened or hoarsened voice, growth of the clitoris, and menstrual irregularities have been reported in women.

DRUG INTERACTIONS

Testosterone cypionate may potentiate oral anticoagulants. Dosage of the anticoagulant may require reduction in order to maintain satisfactory therapeutic hypoprothrombinemia. Concomitant administration of oxyphenbutazone may result in elevated serum levels of oxyphenbutazone.

The metabolic effects of androgens may reduce blood glucose level and insulin in diabetic patients.

ADVERSE REACTIONS

Edema, hypertension, vasodilatation, amnesia, anxiety, dizziness, headache, mental depression, nervousness, sleeplessness, breast soreness, gynecomastia, gonadotropin secretion, growth acceleration, hot flashes, hypercalcemia, hyperchloremia, hypercholesterolemia, hyper-/hypokalemia, hyperlipidemia, hypernatremia, hypoglycemia, libido changes, menstrual problems (including amenorrhea), virilism, gastric irritation, bleeding, vomiting, nausea, cholestatic jaundice, alterations in liver function tests, bleeding, hematocrit / hemoglobin increased, leucopenia, hirsutism, acne, alopecia, dry skin, pruritus and rash. Oligospermia may occur at high dosages.

MISCELLANEOUS Inflammation and pain at the site of intramuscular injection.

CONTRA-INDICATIONS

Cypobolin should not be used in patients with known hypersensitivity to testosterone or any of its excipients.

Contraindicated in males with carcinoma of the breast, known or suspected carcinoma of the prostate gland and in patients with serious cardiac, hepatic or renal disease.

Cypobolin is contraindicated in infant, pregnancy, lactating mothers as testosterone supplements causes fetal harm.

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WARNINGS

Gynecomastia may develop and occasionally persists in patients being treated for hypogonadism. The drug should be discontinued if hypercalcemia may occur in immobilized patients. Edema, with or without congestive heart failure, may be a serious complication in patients with pre-existing cardiac, renal or hepatic disease. Androgen therapy should be used cautiously in healthy males with delayed puberty. The effect on bone maturation should be monitored by assessing bone age of the wrist and hand every 6 months.

PRECAUTIONS

Patients with benign prostatic hypertrophy may develop acute urethral obstruction. Priapism or excessive sexual stimulation may develop. Oligospermia may occur after prolonged administration or excessive dosage. If any of these effects appear, Cypobolin® should be stopped and if restarted, a lower dosage should be utilized. Cypobolin® 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.

STORAGE

Store in a cool dry place below 25°C. Store away from heat, moisture, and light. Keep out of the reach of children.

PRESENTATION

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

MARKETED BY

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