



TESTOSTERONE PROPIONATE

TESTOSTERONE PROPIONATE USP 100mg
Oil Base q.s.
Presented as box with 10 ml vial (multidose)

DESCRIPTION

Testosterone Propionate USP provides testosterone propionate, an esterified derivative of the primary endogenous androgen testosterone for intramuscular use. In bioactive form, androgens have a 17-beta-hydroxy group, the esterification of which produces esters of testosterone which undergo hydrolysis in vivo; producing a delayed release of the bioactive testosterone. Each ml of drug contains 100mg of testosterone propionate in oil base.

INDICATIONS

Males:

Testosterone Propionate Injection is indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone.

Primary hypogonadism : Testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, or orchidectomy.

Hypogonadotropic hypogonadism : Idiopathic gonadotropin or luteinizing hormone — releasing hormone (LHRH) deficiency, or pituitary — hypothalamic injury from tumors, trauma, or radiation. Delayed Puberty : Testosterone Propionate Injection may be used to stimulate puberty in carefully selected males with clearly delayed puberty.

Females:

Metastatic mammary cancer: Testosterone Propionate Injection may be used secondarily in women with advancing inoperable metastatic mammary cancer who are one to five years postmenopausal. It has also been used in premenopausal women who have benefited from oophorectomy and are considered to have a hormone-responsive tumor.

CONTRAINDICATIONS

Androgens are contraindicated in men with carcinomas of the breast or with known or suspected carcinomas of the prostate and in women who are or may become pregnant.

PRECAUTIONS

General: Women should be observed for signs of virilization. Because androgens may alter serum cholesterol concentration, caution should be used when administering these drugs to patients with a history of myocardial infarction or coronary artery disease. All patients: Any nausea, vomiting, changes in skin color or ankle swelling.

DOSAGE AND ADMINISTRATION

Male Androgen Replacement Therapy: Generally 25 to 50 mg injected intramuscularly (IM) 2 to 3 times per week. Titrate to desired serum levels.

Males with Delayed Puberty: Various dosage regimens have been used; some call for lower dosages initially with gradual increases as puberty progresses, with or without a change in maintenance levels. Other regimens call for higher dosages to induce pubertal changes and lower dosages for maintenance after puberty. The chronological and skeletal ages must be taken into consideration, both in determining the initial dose and in adjusting the dose.

Dosage is generally within the lower ranges and only for a limited duration, for example, 4 to 6 months. X-rays should be taken at appropriate intervals to determine the amount of bone maturation and skeletal development.

PRESENTATION

100 mg/ml, 1 x 10 ml vial

STORAGE

Store in a cool dry place (30 °C E 2 °C). Protect from light.

Warming and rotating the ampoule between the palms of the hands will redissolve any crystals that may have been formed during storage at low temperatures