TESTOSTERONE CYPIONATE

TESTOSTERONE CYPIONATE USP 250mg
Oil Base q.s.
Presented as box with 10 ml vial (multidose)

DESCRIPTION
Testosterone Cypionate Injection provides testosterone cypionate, a derivative of the primary endogenous androgen testosterone.

INDICATIONS
Males:
Testosterone Cypionate 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.
Females:
Metastatic mammary cancer: Testosterone Cypionate 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.
When administered to pregnant women, androgens cause virilization of the external genitalia of the female fetus. This virilization includes clitoromegaly, abnormal vaginal development, and fusion of genital folds to form a scrotal-like structure.

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
In 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 decrease to maintenance levels. Other regimens call for higher dosage to induce pubertal changes and lower dosage 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 within the range of 50 to 200 mg every 2 to 4 weeks 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.
Palliation of inoperable mammary cancer in woman: A dosage of 200 to 400 mg every 2 to 4 weeks is recommended. Women with metastatic breast carcinoma must be followed closely because androgen therapy occasionally appears to accelerate the disease.

PRESENTATION
250 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