



TestoGen 250 (Testosterone Enanthate Injection USP)

For I.M. use only

FORMULA

Each ampoule of 1 ml contains: Testosterone Enanthate USP (250 mg), Ethyl Oleate USP (q.s.)

DOSAGE AND USE

Dosage and duration of therapy with Testosterone Enanthate injection will depend on age, sex, diagnosis, patient's response to treatment, and appearance of adverse effects. In general, total doses above 500 mg per month are not required because of the prolonged action of the preparation.

Male hypogonadism: as replacement therapy, i.e., for eunuchism, the suggested dosage is 50 to 500 mg every 2 to 4 weeks.

ADMINISTRATION

Intramuscular injection is to be administered deep into the muscle, due to its oily vehicle. Do not administer intravenously. Shake well before use. Any adverse effect after the use of this product please report in writing to the National Health Surveillance India.

INDICATIONS

Congenital or acquired primary hypogonadism: in cases of testicular failure due to cryptorchidism, bilateral torsion, testicular absence syndrome or orchiectomy.

Hypogonadotropic hypogonadism: in cases of congenital or acquired deficiency of LHRH (luteinising hormone liberating hormone) or hypothalamic pituitary damage due to surgeries, traumas, tumors or radiation.

Delayed Puberty: in cases of history of delayed puberty, not secondary to a pathological disorder, in patients who did not respond to psychological support therapy.

Male Menopause: as replacement therapy in impotence or other symptoms associated to this disorder, when the etiology is due to a confirmed androgen deficiency.

Severe malnutrition.

Specific anemia: aplastic anemia myelofibrosis, myelosclerosis, chronic idiopathic myelofibrosis, hypoplastic anemias caused by malignancies or myelotoxic drugs.

Inoperable breast carcinoma: as palliative secondary – tertiary treatment of metastatic breast cancer in women with hormone-responsive tumors or women that have demonstrated prior response to hormonal therapy.

CONTRAINDICATIONS

This drug is contraindicated in male subjects with breast cancer, diagnosed or suspected prostate cancer or adenoma, severe heart, liver or kidney failure, in prepubertal individuals or in aggressive state, during pregnancy, hypercalcemia.

PRECAUTIONS AND WARNINGS

In palliative treatment of breast cancer do not continue therapy if after three months of treatment ailment continues to develop or hypocalcemia has been reported at any phase of treatment.

Androgen therapy in women, even for a short term, can cause virilization, especially of vocal cords and body hair.

When male subjects over 50 are treated with androgens, there is a bigger risk of prostate enlargement or development of prostate cancer. For this reason, prostate examinations and blood counts must be indicated before prescribing androgens to males within this age range.

During long-term treatment oligospermia, azoospermia or reduced sperm function can occur, resulting in possible infertility, with spontaneous remission after withdrawal of treatment.

Patients with benign prostatic hypertrophy can develop acute urethral obstruction. In this case drugs should be immediately withdrawn.

Calcium levels in serum and urine should be frequently measured in women with metastatic breast carcinoma under testosterone treatment.

During treatment of prepubertal subjects bone x-rays should be performed every six months.

In patients with acute intermittent porphyria, androgens can precipitate seizures of this condition.

ADVERSE REACTIONS

The following reactions require medical supervision:

Virilization and menstrual irregularities in women, irritability of the bladder, gynecomastia. Anaphylaxis, oedema, erythrocytes, gastrointestinal irritation, hypercalcemia and polycythemia, androgenic alopecia, seborrhea and acne in women and men. Carcinoma, prostatic hypertrophy and increased sexual desire.

Adverse reactions of rare occurrence during a long term therapy or with high doses are: hepatic necrosis, leukopenia, liver purpura.

Other adverse reactions are: constipation, nausea, diarrhea, infection, redness, pain or discomfort at injection site, changes in libido, stomach ache, sleeping disorders, impotence, testicular atrophy, headache, anxiety, depression, generalized paresthesia, sleep apnea, rash.

DRUG INTERACTIONS

Testosterone can interact with the following drugs:

• Adrenocorticosteroids, glucocorticosteroids or mineralocorticosteroids: corticotropin, food or drugs that contain sodium (may increase risk of oedema and predispose to acne).

• Oral antidiabetic agents or insulin (because there might be a decrease of glucose serum levels).

• Somatropin

• Hepatotoxic drugs (increase of hepatotoxicity).

OVERDOSE

In case of adverse effects withdraw use of the drug and immediately call your doctor or pharmacist.

PACKAGING

Box with 5 ampoules of 1 ml.

STORAGE CONDITIONS

Store in a cool dry place below 30°C. Do not freeze.

Protect from light. Keep out of reach of children.

Sale only with Prescription.

Made in India

MyoGen™ By Gallene Sciences PVT. LTD.

Ahmedabad, Gujarat 380061, India

myogenlabs.com