



SustaGen 250 (Testosterone Compound Injection)

For I.M. use only

FORMULA

Each ampoule of 1 ml contains: Testosterone decanoate BP (100 mg), Testosterone isocaproate BP (60 mg), Testosterone phenylpropionate BP (60 mg), Testosterone propionate BP (30 mg), Ethyl Oleate BP (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

It is indicated for testosterone replacement therapy; in hypogonadal disorders as: eunuchoidism, hypopituitarism, endocrine impotence, male menopause symptoms such as decreased libido and decay of mental and physical activity, certain types of infertility caused by disturbances of spermatogenesis.

A testosterone therapy might be indicated in cases of osteoporosis caused by androgen deficiency.

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.

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

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

Microphallus Treatment: also called micropenis, a disease in which the child is born with abnormally small penis.

CONTRAINDICATIONS AND RESTRICTIONS

In case of having any of the following diseases: breast tumors in men, prostate tumors, high blood calcium levels, severe liver or kidney failure. This drug must not be used during pregnancy since it has been demonstrated that it produces a high percentage of fetal harm.

PRECAUTIONS AND WARNINGS

Patients with latent or overt cardiac failure, kidney failure, hypertension, epilepsy should be monitored because androgens may induce water and salt retention.

This drug should not be administered to children as it can cause a delay in growth and appearance of signs of early puberty.

Administration of this drug to elderly patients can increase the size of prostate.

It should be administered with caution in case of having any of the following diseases: diabetes, swelling of face, hands or feet, moderate liver failure, enlarged prostate.

ADVERSE REACTIONS AND SIDE EFFECTS

In prepubertal children: precocious sexual development, increased frequency of erection, increase or welding failure of the epiphysis of the bone, excessive development of mammary glands and delayed growth.

Oligospermia or decreased ejaculatory volume.

Salt and water retention.

Priapism or excessive sexual stimulation signals.

When used in high doses in women, testosterone can cause masculinization with signs such as hair growth and hoarse voice that usually disappear when treatment is withdrawn.

DRUG INTERACTIONS

It is important to inform the physician of all medications the patient is consuming because of possible drug interactions. Some of them are:

Anticoagulants: anticoagulant effect may be increased because of decreased procoagulant factor, caused by its decreased synthesis.

Antidiabetic agents (insulin): androgens may decrease blood glucose concentration.

There is drug interaction with: amiodarone, antibiotics, female hormones, oral contraceptives, phenytoin or valproic acid.

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