

TESTOVIRON 100
TESTOSTERONE PROPIONATE
100 mg/mL - MUSCLE
INJECTABLE OIL SOLUTION
Deep intramuscular route

FORMULA

Every 1 ml. of Injectible Oily Solution contains:

Testosterone Propionate100 mg.
Excipients c.s.p.

What is Testosterone Propionate?

It is a medicine that contains a hormone called Testosterone which belongs to the group of Androgens, a group basically responsible for developing and maintaining male sexual characteristics in the body as well as other chronic diseases with hormonal alterations.

How does this medicine work?

It works by activating secondary male sexual characteristics (voice, pubic valley, sexual function, sperm production, erection, sexual desire, body development, muscle mass and correct amount of calcium in bone), red blood cell levels, fat regulation, metabolism of sugars, acts on prostate and liver functions.

What is this medicine for?

For the treatment of all pictures related to disorders of secondary sexual development, whether hormonal or functional in men. Also to treat other chronic diseases related

When not to use this medicine?

If after applying opposite effects and reactions, allergies or adverse symptoms to any of the components of the medication

Therapeutic action

Male Hypogonadism (Congenital or Acquired) Palliative Breast Cancer and secondary to Metastasis by Hormono-Receptive Tumors Low Testosterone Syndrome (SDT), Testicular Failure (Dripotquedism) alterations in Spermatogenesis or infertility of Endocrine origin, Eunuchism, Hypopituitarism, Catabolic States, Osteoporosis of Androgenic origin, Orchiectomy, Endocrine Impotence, Micropenis, Familial Delayed Puberty, Male Climacteric, Hereditary Angioneurotic Edema, Physical Decay, Libido alterations

ACTION MECHANISMS

Testosterone is an androgen hormone derived from Cyclopentanoperhydrophenanthrene, its formula is C₁₉H₂₈O₂ and it is found in a greater proportion in men, since it is produced by the testicles by action and through the Hypothalamic - Pituitary - Testicular axis. In women, it is found in small amounts produced by the ovaries. The Gonadotropin-Releasing Hormone (GnRH) is secreted in the Hypothalamus, which stimulates the Anterior Lobe of the Pituitary gland (Adenohypophysis) which secretes Follicle-stimulating hormones (FSH) and Luteinizing (LH) that are regulated by numerous neurotransmitters. Alpha-adrenergic impulses stimulate GnRH production, and beta-adrenergic and dopaminergic impulses inhibit it. Prostaglandins (Pg) and Noradrenaline increase GnRH secretion. Endorphins, Progesterone, Prolactin and testosterone itself inhibit GnRH secretion especially under stress. GnRH is secreted in amounts every 90-120 min. Therefore, LH regulates Testosterone biosynthesis in Leydig cells located in the testicular interstitium, while FSH stimulates spermatogenesis by acting on Sertoli cells in the seminiferous tubules (Exocrine function) this happens until 80 years of life more or less, spermatogenesis comprises a series of phenomena that cause spermatogonia to become spermatozoa. Therefore Testosterone is produced from cholesterol in Leydig cells, under the influence of LH. Mitochondrial enzymes cleave the cholesterol side chain to form Pregnenolone. Other enzymes are involved in various biosynthetic steps to ultimately form testosterone and the sequence that follows is as follows: Pregnenolone, Progesterone, Dihydroepiandrosterone, Androstenediol and finally Testosterone. In Sertoli cells, a hormone called Inhibin is produced, which acts by stopping or suppressing the release of FSH. It is also known that Testosterone itself and Estradiol are capable of I and LH Testosterone is a hormone that belongs to the group of Androgens and is chemically related as a Prohormone. Free Testosterone diffuses into target cells where it can be metabolized to another more active androgen, 5-Alpha-Dihydrotestosterone (5-α DHT) by 5α-Reductase and Estradiol by the action of aromatase, this being the active principle. There are 2 isoenzymes of 5α-reductase, Type I (skin and liver) and Type II (adrenal gland, prostate, seminal vesicle, genital skin, hair follicle and cerebral cortex). At many sites of action Testosterone is not the active form of the hormone, Dihydrotestosterone binds to an intracellular receptor protein and this complex is fixed in the nucleus to specific hormone regulatory elements on the chromosomes and acts to increase RNA and protein you specify, 90% of Testosterone is secreted by Leydig cells in the healthy adult male and 5 to 10% by the adrenal glands, the latter having very little effect on testicular function. Testosterone is a polyphasic hormone in the blood. It is transported bound to proteins in 98% and 2% of the liter signature (shape, that circulating amount 60% binds to the Sex Hormone Binding Globulin (SHBG) produced mainly by the liver, the other 38% joins the allows it to enter the target organ, that is, it is Bioavailable Testosterone, which has the greatest hormonal action. Testosterone is produced between 5 and 7 mg horribly in adults and regulated by the circadian rhythm with variations of up to 38% in early in the morning (sample language opuma). Testosterone is inactivated primarily in the liver. Testosterone injected as an oil solution is rapidly absorbed, metabolized, and excreted so that the androgenic effect. Testosterone is metabolized in the liver by oxidation through the 17-OH group and becomes Androstenedione, to then weakly turn to the derivative in Androstenedione and Elicholanone (inactive) excreted in urine as Sulfates and Glucuronocoon played, 6% goes through feces for Enterohepatic recirculation. The most active derivative of Testosterone is Dihydrotestosterone, in various target organs by 5α-reductase. In addition to the aromatization of small amounts of testosterone, giving rise to Estrogenic derivatives. Testosterone Propionate is particularly active parenterally.

BIOLOGICAL EFFECTS OF TESTOSTERONE

- **Wolffian duct:** Stimulates growth and differentiation; **External genitalia:** Masculinization and Growth; **Bones:** Closure of the epiphyses; **Larynx:** Cord growth and lengthening vowels; **Fur:** Stimulates the production of fat stimulates the growth of body and facial hair decreases hair growth (androgenic alopecia) **Kidneys:** Stimulates the production of erythropoietin; **Liver:** induces enzymes, influences protein synthesis, Lipid metabolism: tHDL cholesterol and LDL; **Bone marrow:** Stimulates erythropoiesis; **Muscles:** Lean fat development; **Testicle:** stimulates and maintains Spermatogenesis; **Prostate:** Stimulates its growth function; **mons:** inhibits its growth; **Hypophysis:** negative feedback of

GnRH secretion, Brain: Psychotropic effects on libido.

CONTRAINDICATIONS

-Cardiovascular Diseases, Arterial Hypertension, Diabetes, Thyroid and Adrenal Diseases, Convulsive (epilepsy) and Prostatic Diseases, (Cancer) Active Breast Cancer, Kidney Diseases, Liver Diseases of any etiology, Pregnancy, Severe osteoporosis, Lactation, Anemia (especially hormonal or androgenic type) This medicine contains peanut oil (peanut) should not be used in cases of allergy to peanuts Known hypersensitivity to the active substance or to any excipient of the formulation and is contraindicated in women.

WARNINGS AND CAUTIONS

-It should not be used for long periods. Do not administer to patients with other treatments. Do not consume alcohol simultaneously. Do not exceed doses **Do not use in pregnant women.** Administer with caution to patients allergic or sensitive to this medication or its components. Androgens are not appropriate for increasing muscle development or strength, physical capacity in healthy individuals - **Pre pubescent children:** monitor height due to accelerated premature epiphyseal closure and sexual maturation.

Who should be careful when using this medication?

Those with heart disease, high blood pressure, tumors, breast and prostate cancer, alterations in cholesterol and triglycerides, liver problems, poor kidney function, epilepsy, unbalanced calcium in the blood, diabetes, thyroid, patients with metastases of any variety.

What groups of people should be especially careful with this medicine?

All women, children and adolescents and the elderly. Pregnant and lactating women as it is potentially risky. It should not be administered to those who receive other treatments, they must necessarily consult their doctor.

ADVERSE REACTIONS

-The appearance of adverse reactions can be: In pre-pubertal children (premature sexual maturation and growth arrest); In adults (Priapism, Acne, moderate polycythemia and obstruction by Prostatic Hypertrophy) decrease in HDL, Elevation of other lipid fractions, Liver Diseases (Cholestatic Jaundice), Hepatic Carcinoma, Prostate Cancer (before the age of 50), Hydrosaline retention, Edema (more in Neoplasms), Arterial Hypertension, decreased spermatogenesis in men with feminizing effects, (Gynecomastia, decreased libido, probable erection disorders and androgenic-type impotence) Imbalance of Calcium values (Osteoporosis), increased Glycemia levels, alterations thyroid hormones, Nephropathies and alteration of the Adrenals.

DRUG INTERACTIONS

- Barbiturates: Microsomal enzyme inducers, alter clearance. Oxyphebutazone: Its levels increase. Ac. Valproic, Amlodarone, Antibiotics, Phenytoin, Oral Anticoagulants: Coumarinics with increased activity (check dose) INR and Prothrombin control; Hypoglycemic agents: They enhance their action by reducing the levels of Insulin - ACTH and corticosteroids: formation of edema.

GENERAL SUGGESTIONS AND TIPS

- **Doctors should monitor 3 (three) months, at 6 (six) and at 12 (twelve) months, those who have Testosterone treatment under the following parameters**

-Rectal examination and Prostate Specific Antigen (PAS) to rule out hyperplasia or subclinical prostate cancer (more in older adults)

- Hematocrit and Hemoglobin to rule out Polycythemia Vera (overproduction of Red Blood Cells).

-Sleep Apnea, especially patients with Pulmonary disorders (COPD, EBCC)

POSOLOGY

10-50mg, of Oily Solution 2 to 3 times a week, via Deep Intra Muscular or according to medical criteriaHypogonadism (adults) 10 - 50 mg Deep Intramuscular route, 2 to 3 times a week and under MEDICAL CONTROLIn case of Renal Insufficiency, tests must be carried out previously and consult with the Nephrologist, but the average dose is 25 mg, dial for 10 days maximum or as directed by your doctor.ATTENTION II Warnings for athletes have not been described, but it is reported that this medicine contains a component that in an anti-doping test gives the result as POSITIVE (+)

OVERDOSE

-Quickly resort in Paraguay to the Toxicology Center of the Hospital for Medical Emergencies

PRESENTATION

Box containing 1 vial with 10 ml injectable oily solution

Box containing 1.5 ampoule with injectable oily solution X 1ml

Mantener a una temperatura inferior a 25°C en lugar seco
y fuera del alcance de los niños