

MUSCLELABS
TESTOVIRON 250mg/ml
INJECTABLE

FORMULA:

Every 1 ml. contains:

Testosterone Enanthate.....250 mg.

Excipients.....c.s.p.

PROPERTIES:

Testosterone, the main sexual androgen, is responsible for the development and maintenance of male secondary sexual characteristics, exerting an important anabolic action. This last property contributes, above all, to the acceleration of the growth process during puberty, stimulating bone growth and modulating the welding process of the epiphysis of long bones. In normal humans, it stimulates the activity of the RNA polymerase enzyme and the synthesis of specific RNA, resulting in increased protein production. Testosterone stimulates the production of erythrocytes because it favors the synthesis of erythropoiesis-stimulating factors.

Alterations in protein metabolism that cause loss of muscle mass and negative nitrogen balance, such as in cases of severe malnutrition, prolonged treatment with high doses of corticosteroids, after major surgery, anticancer treatment, burns and other processes. Postmenopausal or senile osteoporosis. Breast carcinoma. Palliative treatment in certain cases of disseminated breast cancer. Anemia associated with chronic renal failure. In the treatment of hereditary angioedema. In the treatment of cryofibrinogenemia, reducing the severity and frequency of attacks. Increases muscle mass in athletes

INDICATIONS:

- Congenital or acquired primary hypogonadism: When there is testicular failure due to cryptorchidism, bilateral torsion, testicular absence syndrome or orchiectomy.
- Hypogonadotropic hypogonadism: When there is congenital or acquired deficiency of LH-RH (luteinizing hormone releasing hormone) or hypothalamic-pituitary deficiency due to surgery, trauma, tumors or radiation.
- Delayed puberty: when there is a family pattern of delayed puberty, not secondary to a pathological disorder, in patients who have not responded to supportive psychological therapy.
- Male climacteric: As replacement therapy for impotence or other symptoms associated with this disorder, when the etiology is due to a verified androgen deficiency.
- Severe malnutrition.
- Specific anemias: myelofibrous aplastic anemia, myelosclerosis, agnogenic myeloid metaplasia, hypoplastic anemias caused by malignancy or myelotoxic drugs.
- Inoperable breast carcinoma: As palliative treatment of secondary and tertiary metastatic breast cancer in women with hormone-receptive tumors or in those who have demonstrated a prior response to hormonal therapy.

ADVERSE REACTIONS:

The following adverse reactions require medical supervision: Virilization and menstrual irregularities in women, bladder irritability, gynecomastia, Anaphylaxis, edema, erythrocytosis, gastrointestinal irritation, hypercalcemia and polycythemia, androgenic alopecia, seborrhea and acne in men and women. Prostatic hypertrophy carcinoma and increased sexual desire. Adverse reactions are: Constipation, nausea, diarrhea, infection, redness, pain or irritation at the injection site, changes in libido, stomach pain, difficulty sleeping, impotence, testicular atrophy, headaches, anxiety, depression, generalized paresthesia, sleep apnea, skin irritation.

CONTRAINDICATIONS:

It is contraindicated in patients with male breast cancer, diagnosed or suspected prostate cancer or adenoma, severe heart, liver or kidney failure, prepubertal or aggressive individuals, pregnancy and hypercalcemia.

DOSAGE:

- Hypogonadism, climacteric or impotence (male replacement therapy): 50 to 400 mg IM every 2 to 4 weeks.
- Male delayed puberty (replacement therapy): 25 to 200 mg every 2 to 4 weeks for a period generally limited to 6 months.
- Antineoplastic, in inoperable breast cancer (female): 200 to 400 mg IM every 2 to 4 weeks.

PRECAUTIONS AND WARNINGS:

In the palliative treatment of breast cancer, do not continue therapy if the disease persists after 3 months or if hypocalcemia is observed at any stage of the disease. Androgenic therapy in women, even if short-term, can produce virilization, especially vocal and hairy. Androgen therapy is inadvisable for improving athletic performance. In children, this medication should be used with caution due to adverse effects on the bone maturation process, which can be accelerated without producing compensatory gains in linear growth. When male patients over 50 years of age are treated with androgens, the risk of enlarged prostate or developing prostate cancer becomes greater. For this reason, prostate and blood tests are often performed before prescribing androgens for men of this age. During prolonged treatment, oligospermia, azoospermia or reduced sperm function may occur, resulting in possible infertility, with spontaneous remission after discontinuation of treatment. Patients with benign prostatic hypertrophy may develop acute urethral obstruction, requiring immediate discontinuation of the medication. Serum and urinary calcium levels should be determined frequently in women with metastatic breast carcinoma treated

with testosterone. During treatment in prepubertal minors, bone x-rays should be taken every 6 months. In patients with intermittent watery porphyria, androgens may precipitate attacks of this condition. It is generally preferable to start treatment with full doses and subsequently adjust to individual characteristics.

DRUG INTERACTIONS:

- Testosterone may interact with the following medications: Adenocorticoids, glucocorticoids or mineralocorticoids: corticotropin, sodium-containing foods or medications (may increase the risk of edema and predispose to acne). Oral antidiabetics or insulin: (because there may be a reduction in serum glucose levels). Somatotropin. Hepatotoxic drugs: (hepatotoxicity is increased)
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- Oral antidiabetics or insulin: (because there may be a reduction in serum glucose levels).
- Hepatotoxic drugs: (hepatotoxicity is increased)

OVERDOSE:

Doses frequentes podem desencadear sintomas de remissão lenta, por ser um medicamento de ação prolongada. Recomenda-se a suspensão imediata da medicação.

RECOMENDATIONS:

- Using a wet needle or syringe may cause cloudiness of the solution, which does not affect the effectiveness of the medicine. If crystals form in the bubbles, gentle heating by rubbing between your hands or shaking may dissolve the crystals.
- The intramuscular injection must be administered deep into the gluteal or deltoid muscle. Do not administer intravenously.
- Store at 15 – 30°C and protect from freezing. Shake before using.

PRESTATION:

Box containing a 10 mL vial

**Store at a temperature below 25°C in a dry place
and out of the reach of children.**