Sustanon® “250”

Oily solution for intramuscular injection

Composition

Each ml of the oily solution contains:
Testosterone propionate 30 mg
Testosterone phenylpropionate 60 mg
Testoerone isohexanoate 60 mg
Testosterone decanoate 100 mg

Inactive ingredients: Benzyl alcohol, arachis oil.

Characteristics

Sustanon “250” is an androgenic preparation for intramuscular administration containing four different esters of the natural hormone testosterone. Testosterone propionate has a rapid onset and a short duration of action. Testosterone phenylpropionate and isohexanoate have a less rapid onset and a long duration of action. Testosterone decanoate has a slow onset and a long duration of action.
By combining these testosterones eaters, the action of Sustanon “250” starts shortly after injection and is maintained for about three weeks.
Sustanon “250” is generally well tolerated and has no adverse effect on the liver.

Indications

Testosterone replacement therapy in male hypogonadal disorders, for example:

- after castration;
- eunuchoidism;
- hypopituitarism;
- endocrine impotence;
- male climacteric symptoms such as decreased libido and decreased mental and physical activity;
- certain types of infertility due to disorders of spermatogenesis.

Moreover, testosterone therapy may be indicated in osteoporosis due to androgen deficiency.

Dosage

In general, dosage should be adjusted according to the response of the individual patient.
Usually, one injection of 1 ml per three weeks is adequate.

Administration

Sustanon “250” should be administered by deep intramuscular injection.

Contra-Indications

Known or suspected prostatic or mammary carcinoma.

Warnings and precautions

- If androgen associated adverse reactions occur, treatment should be interrupted and, after disappearance of the symptoms, be resumed at a lower dosage.
- Patients, especially the elderly, with the following conditions should be monitored: ischemic heart disease, since androgens may produce hypercholesterolaemia.
- Latent or overt cardiac failure, renal or hepatic dysfunction, hypertension, epilepsy or migraine (or a history of these conditions), since androgens may occasionally induce salt and fluid retention.
- Skeletal metastases, since androgens may induce hypercalcemia or hypercalciuria in these patients.
- Males, especially geriatric patients, may become overly stimulated. Stimulation to the point to increasing the nervous, mental and physical activities beyond the patient's cardiovascular capacity should be avoided when testosterone is used to treat climacteric in males.
  Geriatric males may be at increased risk of developing prostatic hypertrophy and carcinoma during androgen therapy.
- Patients receiving high dosages of testosterone should have periodic hemoglobin and hematocrit determinations, since polycythemia may occur.
- Androgens should be used cautiously in prepubertal boys to avoid premature epiphyseal closure or precocious sexual development.
- A decrease in protein- bound iodine (PBI) may occur, but this has no clinical significance.
- The misuse of androgens to enhance ability in sports carries serious health risks and is to be discouraged.

Drug interactions

- Testosterone may potentiate the action of oral anticoagulants, causing bleeding in some patients. When testosterone therapy is initiated in patients receiving oral anticoagulants, dosage reduction of the anticoagulants may be required to prevent and excessive hypoprothrombinemic response. Patients receiving oral anticoagulants should also be closely monitored when androgen therapy is discontinued.
- Increased serum oxyphenbutazone concentrations have reportedly occurred in patients receiving androgens concurrently with oxyphenbutazone.
- The metabolic effects of androgens may decrease blood glucose concentrations and insulin requirements in patients with diabetes.

- Combination with other, hepatotoxic medications, may result in an increase incidence of hepatotoxicity: patients should be carefully monitored, especially those on prolonged administration or those with a history of liver disease.

Adverse reactions

The following adverse reactions have been associated with androgen therapy: Acne, flushing of the skin, gynecomastia, increased or decreased libido, habituation and edema. If edema is present before or develops during therapy, administration of diuretic may be required.

- Priapism and other signs of excessive sexual stimulation.
- In prepubertal boys, precocious sexual development, an increased frequency of erections, phallic enlargement and premature epipyseal closure.
- Oligospermia and decreased ejaculatory volume.
- Retention of water, sodium chloride, potassium, and inorganic phosphates.
- Hypersensitivity reactions, including skin manifestations and anaphylactoid reactions, have occurred rarely with testosterone.
- Hypercalcemia resulting from osteolysis, especially in immobile patients has been reported in patients receiving testosterone. The drug should be discontinued if hypercalcemia occurs in patients with cancer, since this may indicate progression of metastases to the bone.
- Cholestatic hepatitis and jaundice and abnormal liver function test results have occurred in patients receiving androgens.
- Other adverse effects associated with testosterone therapy include nausea, epididymitis, bladder irritability, chills, excitation and sleeplessness, headache, anxiety, mental depression, generalized paresthesia, leucopenia, polycycthemia, and suppression of clotting factors II, V, VII and X. Serum cholesterol concentration may increase during androgen therapy. IM administration of anabolic steroids has been associated with urticaria and inflammation at the injection site, postinjection induration, and furunculosis.

Pharmaceutical precautions

Store in the original package.
Store below 30˚C. Do not refrigerate or freeze.
After storage at lower temperatures precipitation of the oil vehicle may occur. By heating the ampoules at 100˚C for a few minutes or at 40˚C for one hour, the solution will become clear. The precipitation and rewarming does not affect the activity of the injection.

Package quantities:

1 ml ampoule in boxes of 1.

In correspondence please quote packing number.

Manufacturer: N.V. Organon, Oss, the Netherlands.
Registration Holder: Perrigo Israel Agencies Ltd., 29 Lehi St., Bnei-Brak 51200.

The content of this leaflet was checked and approved by the Ministry of Health in October 2004.

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