Primus Ray
Laboratories

TESTOSTERONE COMBO 250

is used to treat for testosterone replacement therapy in male hypogonadal disorders. It is an oil-based injectable containing four different testosterone esters: testosterone propionate (30 mg); testosterone phenyl propionate (60 mg); testosterone isocaproate (60mg); and testosterone decanoate (100 mg). It is an intelligently “engineered” blend designed to provide a fast yet extended release of testosterone. Thus it can provide significant gains in strength and muscle tissue, as well as a noticeable increase in libido. The propionate and phenyl propionate esters in this product are quickly utilized, releasing into circulation within the first four days. The remaining esters are much slower to release, staying active in the body for approximately two and three weeks. It has a strong anabolic activity, with a pronounced androgenic component.

TESTOSTERONE COMBO 250 is approved for the following uses:
Testosterone replacement therapy
In conditions associated with a testosterone deficiency such as:

- Testosterone replacement therapy in male hypogonadal disorders
- Osteoporosis due to androgen deficiency

Chemical: Testosterone 250mg/ml
Testosterone Propionate BP 30mg
Testosterone Phenylpropionate BP 60mg
Testosterone Isocaproate BP 60mg
Testosterone Decanoate BP 100mg
Chemical Name: 17ß-hydroxyandrost-4-en-3-one
Molecular Formula: C19-H28-O2
Molecular Weight: 288.429
Melting point: mp 155°

Prescription Medicine

TESTOSTERONE COMBO 250
Testosterone Compound 250 mg
Oil base q.s.

DESCRIPTION

Testosterone Compound is an androgenic preparation for intramuscular administration containing four different esters of the natural hormone testosterone.
INDICATIONS

Testosterone replacement therapy in male hypogonadal disorders, for example:

- After castration
- Eunuchoidism
- Hypopituitarism

CONTRAINDICATIONS

Known or suspected mammary or prostatic carcinoma in the male. This medicine is not intended for use in female patients.
This preparation is also contraindicated in patients with a history of hypersensitivity to any of its components.
Woman who are or may become pregnant
Benign prostatic hyperplasia with obstruction
Undiagnosed genital bleeding
Severe kidney and heart failure

WARNINGS

Middle-aged and elderly males with angina pectoris or other severe circulatory disease should receive androgen treatment only under very careful supervision.
DRUG INTERACTIONS

Drug Interactions

When administered concurrently, the following drugs may interact with androgens, have been reported to decrease the anticoagulant requirement.
Patients receiving oral anticoagulant therapy require close monitoring especially when androgens are started or stopped.
Antidiabetic agents oral or insulin.
Cyclosporine
Hepatotoxic medications,other
Human growth hormone (Somatropin)

DOSAGE AND ADMINISTRATION

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

TESTOSTERONE COMBO 250 should be administered by deep intramuscular injection.

SIDE EFFECTS AND SPECIAL PRECAUTIONS

The following adverse reactions have been associated with androgen therapy:

Priapism and other signs of excessive sexual stimulation.
In prepubertal boys: precocious sexual development, an increased frequency of erections, phallic enlargement and premature epiphyseal closure.
Oligospermia and decreased ejaculatory volume.
Water and salt retention
Skin : virilism
Nervous: insomnia, headache, depression
Liver : cholestatic hepatitis
Kidney : bladder irritability or urinary tract infection

PRECAUTIONS

If an androgen-associated adverse reaction occurs, treatment should be interrupted and, after disappearance of the symptoms, be resumed at a lower dosage. Patients with latent or overt cardiac failure, renal dysfunction, hypertension, epilepsy or migraine (or a history of these conditions) should be monitored, since androgens may occasionally induce salt and fluid retention. Androgens should be used cautiously in pre-pubertal 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. Treatment of male patients over the age of approximately 50 years with androgens should be preceded by a thorough examination of prostate and baseline measurement of prostate-specific antigen serum concentration.

PATIENT MONITORING

Bone age determinations
Cholesterol and/or HDL and LDL
Hemoglobin and Hematocrit determinations
Hepatic function determinations
Prostatic acid phosphatase and prostatic specific antigen
Testosterone, total, serum

For treatment of breast carcinoma

Alkaline phosphatase, serum values and physical examination and x-rays of known or suspected metastases
Calcium

For gender change androgen therapy

LH, ALT [SGPT]

PRESENTATION

250 mg/ml, 10 x 1 ml cartridges

STORAGE

Store in a cool dry place (< 25ºC)
Protect from light.
Warming and rotating the vial between the palms of the hands will redissolve any crystals that may have been formed during storage at low temperatures.

Manufactured by: Primus Ray Laboratories