

Testoren®

Iron Sucrose injection USP

Description

Testoren® is a preparation of Testosterone Propionate, Testosterone Phenylpropionate, Testosterone Isocaproate and Testosterone Decanoate. All four compounds are esters of the natural hormone testosterone. Testosterone is the principle endogenous hormone which is essential for normal growth and development of the male sex organs and male secondary sex characteristics. During adult life Testosterone is essential for the functioning of the testes and accessory structure and for the maintenance of libido, sense of wellbeing, erectile potency, prostate and seminal vesicle function.

Indications

Males: Testoren® is indicated for Testosterone replacement therapy for primary and secondary hypogonadal disorders, which include:

- After castration
- Eunuchoidism
- Hypopituitarism
- Endocrine impotence
- Certain types of infertility due to spermatogenic disorders
- Male climacteric symptoms as decreased libido and decreased feeling of general wellbeing and fitness
- Osteoporosis caused by androgen deficiency

Female to male transsexuals: Testoren® is indicated for masculinization.

Dosage and administration

In general, the dose should be adjusted according to the response of the individual patient.

Adults: Usually, one injection of 1 ml per three weeks is adequate. **Testoren®** should be administered by deep intramuscular injection.

Children: Safety and efficacy have not been adequately determined in children and adolescents. **Testoren®** contains benzyl alcohol and should not be given to children under 3 years of age.

Use in pregnancy and lactation

Pregnancy: There are no adequate data for the use of Testosterone in pregnant women. In view of the risk of virilization of the foetus, Testosterone should not be used during pregnancy. Treatment with Testosterone should be discontinued when pregnancy occurs.

Lactation: There are no adequate data for the use of Testosterone during lactation. Therefore, Testosterone should not be used during lactation.

Side effects

The most common side effects of Testosterone therapy are precocious sexual development, increased frequency of erections, phallic enlargement and premature epiphyseal closure, priapism, oligospermia, decreased ejaculatory volume and fluid & sodium retention.

Contraindications

Testosterone is contraindicated in case of known hypersensitivity to Testosterone or any of its components. It is also contraindicated in patient with known and suspected prostatic carcinoma or breast carcinoma in male.

Warnings and Precautions

Androgens should be used with caution in pre (pubertal) boys to avoid premature epiphyseal closure or precocious sexual development. Skeletal maturation should be monitored regularly. Patients with latent or overt cardiac failure, renal dysfunction, hypertension, epilepsy or migraine (or a history of these conditions) should be kept under close medical supervision, since aggravation or recurrence may occasionally be induced. Androgens should be used with caution in men suffering from benign prostatic hyperplasia. The use of steroids may influence the results of certain laboratory tests. The misuse of androgens to enhance ability in sports carries serious health risks and is to be discouraged.

Drug interaction

Enzyme inducing agents may exert increasing or decreasing effects on Testosterone levels. Therefore, adjustment of dose or intervals between injections may be required.

Overdose

The acute intramuscular toxicity of Testosterone is very low. Priapism in men is a symptom of chronic over dosage. If this occurs, treatment should be interrupted and after disappearance of the symptom, be resumed at a lower dosage.

Pharmaceutical precautions

Store in a cool (between 8° C to 30° C) and dry place protected from light. Keep out of the reach of children.

Presentation

Testoren® injection: Each 1 ml ampoule contains Testosterone Propionate BP 30 mg, Testosterone Phenylpropionate BP 60 mg, Testosterone Isocaproate BP 60 mg and Testosterone Decanoate BP 100 mg in Arachis Oil. All four compounds are ester of the natural hormone Testosterone. The oily solution also contains 10 percent Benzyl Alcohol.

Package quantities

Testoren® injection: Carton of 1 ml ampoule in blister strip.

® Registered Trade Mark



ACI Limited

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