

ARROW - TESTOSTERONE

testosterone undecanoate 40mg capsule

This product may not be interchangeable with other products containing this ingredient in the New Zealand Market

Presentation

Arrow – Testosterone is oval, orange clear, soft gelatin capsule, ink-printed in white with "P" logo and "40" on the same line.

Uses

Actions

Testosterone is the principal endogenous hormone 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 structures, and for the maintenance of libido, sense of well-being, erectile potency, prostate and seminal vesicle function.

Treatment of hypogonadal males with testosterone results in a clinically significant rise of plasma concentrations of testosterone, dihydrotestosterone and androstenedione, as well as a decrease of SHBG (sex hormone binding globulin). In males with primary (hypergonadotropic) hypogonadism treatment with testosterone results in a normalization of gonadotrophin levels.

Pharmacokinetics

Following oral administration, part of the testosterone undecanoate is co-absorbed with the lipophilic solvent from the intestine into the lymphatic system, thus circumventing the first-pass inactivation by the liver. During absorption testosterone undecanoate is partly reduced to dihydrotestosterone undecanoate. From the lymphatic system it is released into the plasma. In plasma and tissues both testosterone undecanoate and dihydrotestosterone undecanoate are hydrolysed to yield the natural male androgens testosterone and dihydrotestosterone. Single administration of 80-160mg testosterone leads to a clinically significant increase of total plasma testosterone with peak-levels of approximately 40 nmol/L (C_{max}) reached approximately 4-5 hours after administration (t_{max}). Plasma testosterone levels remain elevated for at least 8 hours. Testosterone and dihydrotestosterone are metabolised via the normal pathways. Excretion mainly takes place via the urine as conjugates of etiocholanolone and androsterone.

Indications

In the male

Testosterone replacement therapy for primary or secondary 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 in the male due to androgen deficiency.

Dosage and Administration

Dosage

In general, dosage should be adjusted according to the response of the individual patient. Usually, an initial dosage of 120 – 160 mg daily for 2 - 3 weeks is adequate, followed by a maintenance dosage of 40 – 120 mg daily.

Administration

ARROW - TESTOSTERONE capsules should be taken after meals, with a little fluid if necessary, and swallowed whole without chewing. It is preferable that half of the daily dose be taken in the morning and the other half in the evening. If an uneven number of capsules are to be taken, the larger dose should be taken in the morning.

Contraindications

Known or suspected prostatic or mammary carcinoma.

Warnings and Precautions

- If androgen-associated adverse reactions occur, ARROW - TESTOSTERONE 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 aggravation or recurrence may occasionally be induced.
- Androgens should be used cautiously in prepubertal boys to avoid premature epiphyseal closure or precocious sexual development. Skeletal maturation should be monitored regularly.
- The use of steroids may influence the results of certain laboratory tests.
- Androgens should be used with caution in men suffering from benign prostatic hypertrophy.

Pregnancy and lactation

ARROW-TESTOSTERONE should not be used in pregnancy and lactation.

Effects on ability to drive and use machines

As far as is known, ARROW-TESTOSTERONE has no adverse effect on alertness and concentration.

Adverse Effects

The following adverse reactions have been associated with androgen therapy in general:

- In men: priapism and other signs of excessive sexual stimulation, oligospermia and decreased ejaculatory development.
- In prepubertal boys: precocious sexual development, an increased frequency of erections, phallic enlargement and premature epiphyseal closure.
- In all patients: water and salt retention.

Interactions

Enzyme-inducing agents may exert increasing or decreasing effects on the testosterone levels. Therefore adjustment of dose for ARROW - TESTOSTERONE may be required.

ARROW-TESTOSTERONE must be taken with a meal to establish appropriate plasma testosterone levels.

Overdosage

The acute oral toxicity of testosterone undecanoate is very low. High dosages of ARROW - TESTOSTERONE may cause gastrointestinal complaints due to the oily solvent contained in the capsules. Treatment may consist of emptying the stomach and supportive measures.

Pharmaceutical Precautions

Store below 25 °C. Protect from light and moisture.

Medicine Classification

Prescription Medicine.

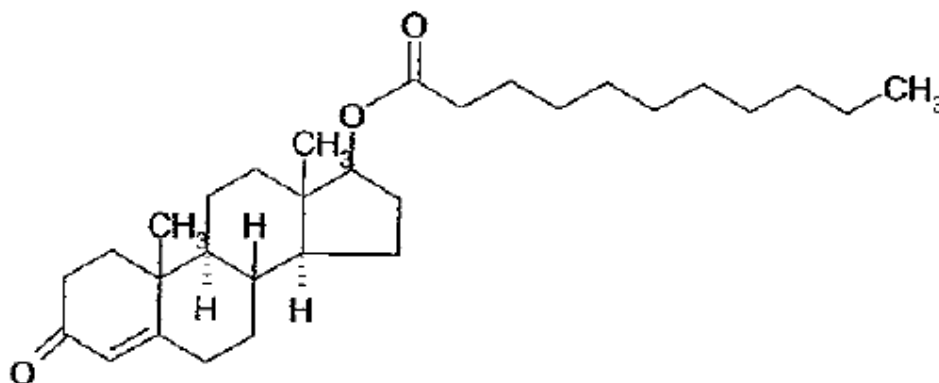
Package Quantities

HDPE bottle pack containing 100 capsules.

PVC/PVDC blister pack containing 60 capsules (not marketed).

Further Information

INN: Testosterone Undecanoate



Molecular formula: C₃₀H₄₈O₃

Molecular weight: 456.706 g/mol

CAS No. 5949-44-0

Testosterone undecanoate is a white to almost white waxy crystalline powder. Odourless or with a slight characteristic odour. It is insoluble in water, freely soluble in acetone, dioxane and chloroform; soluble in vegetable oils.

Preclinical safety data

Preclinical data reveal no hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential and toxicity to reproduction.

List of excipients

Each ARROW-TESTOSTERONE capsule contains caprylic-capric acid tryglicerides. The capsule shells contain the following excipients: gelatine, glycerin, sorbitol, methylparaben sodium and propylparaben sodium. The capsules are printed with ink comprising of white Opacode Ink and # 6 Yellow D & C.

Name and address

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DATE OF PREPARATION

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