



Testosterone Undecanoate 40 mg capsules

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Active Ingredients:
Each soft gelatin capsule contains 40 mg testosterone undecanoate dissolved in oleic acid.

• COMPOSITION

Each capsule contains 40 mg testosterone undecanoate dissolved in oleic acid.

PHARMACOLOGICAL CLASSIFICATION

A 21.7 Male sex hormones



PHARMACOLOGICAL ACTION

The active substance is testosterone undecanoate, a fatty acid ester of the natural androgen testosterone. Testosterone undecanoate is able to bypass the liver via the lymphatic system and is therefore orally active. Therapy with Testosterone Undecanoate capsules increases plasma levels of testosterone and its active metabolites.

• INDICATIONS

Testosterone replacement therapy in male hypogonadal disorders, for example:

- after castration;
- eunuchoidism;
- hypopituitarism.

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

CONTRA INDICATIONS

Impaired hepatic function and hypercalcaemia.

Known or suspected mammary or prostatic carcinoma.

• WARNINGS

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

DOSAGE AND DIRECTIONS FOR USE

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

Usually, an initial dosage of 120-160 mg daily for 2 to 3 weeks is adequate, followed by a maintenance dosage of 40 120 mg daily.

Administration:

testosterone undecanoate capsules should be taken after meals, with a little fluid if necessary, and swallowed 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 is to be taken, the larger dose should be taken in the morning.

SIDE EFFECTS AND SPECIAL PRECAUTIONS

The following adverse reactions have been associated with androgen therapy:

- Priapism and other signs of excessive sexual stimulation.
- Oligospermia
- Water and salt retention.

In prepubertal boys androgen therapy is problematic as precocious sexual development, and increased frequency of erections, phallic enlargement and premature epiphyseal closure may occur.

Special precautions:

If androgen associated adverse reactions occur, 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 induce salt and fluid retention.

A decrease in protein bound iodine (PBI) may occur, but this has no clinical significance.

Testosterone Undecanoate capsules

• **KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:**

See Side effects and Special Precautions.
Treat symptomatically.

• **CONDITIONS OF REGISTRATION:**

Advertising to the professions only.

• **IDENTIFICATION:**

Soft, reddish brown gelatin capsules with the code 'ORG' on one side and the code 'DV3' on the reverse side.

• **PRESENTATION:**

Securitainers with 60 capsules.



STORAGE INSTRUCTIONS:

For wholesale and pharmacies: Store at 2-8°C.

After dispensing: Store at room temperature, below 30°C, in a dry place, for no longer than 90 days. Protect from light.

Keep out of reach of children.

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According to the Indian Trade Mark the company owns about 450 brands and 4600 generic manufacturing permissions in India. According to the export data analysis the company was the largest exporter of generic medicines to the Europe and Middle East countries.

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The company medicines are present in France, Georgia, Egypt and CIF countries.



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