Testosterone Undecanoate 40 mg capsules

Testosterone Undecanoate capsules

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
A21.7 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;
- hypogonituitarism.
Moreover, testosterone therapy may be indicated in osteoporosis due to hypoandrogenal 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.

DOSEAGE 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.
- Oligosper
- 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 40 mg capsules

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.

Note: This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world. The Price of the drugs indicated above may not match the actual price at which they are sold. Prices can change depending on many factors, including local taxes. These are only approximate indicative prices of the drug. The products discussed herein may have different product labeling in different countries. The product information provided in this site is intended only for the residents of India.

Information for Health Care Professionals

*** Please consult local Prescribing Information for any product before use. This website is an international information resource for healthcare professionals with an interest in disease management. This website is not intended to replace the advice of a qualified healthcare professional. Above brand is a trademark of the Taj group of companies (Taj Pharmaceuticals Limited).

Taj Pharmaceuticals Group
This document includes statements that are, or may be deemed to be, “forward-looking statements”. These forward-looking statements can be identified by the fact that they do not only relate to historical or current events. Forward-looking statements often use words such as “anticipate”, “target”, “expect”, “estimate”, “intend”, “expected”, “plan”, “goal”, “believe”, or other words of similar meaning. By their nature, forward-looking statements involve risk and uncertainty because they relate to future events and circumstances, a number of which are beyond Company’s control. As a result, actual future results may differ materially from the plans, goals and expectations set out in these forward-looking statements. Any forward-looking statements made by or on behalf of the Company speak only as at the date of this announcement. Save as required by any applicable laws or regulations, the Company undertakes no obligation publicly to release the results of any revisions to any forward-looking statements in this document that may occur due to any change in its expectations or to reflect events or circumstances after the date of this document. The securities referred to herein have not been and will not be registered under the US Securities Act of 1933, as amended (the “Securities Act”), and may not be offered or sold in the United States or to US persons unless the securities are registered under the Securities Act, or an exemption from the registration requirements of the Securities Act is available. No public offering of the securities will be made in the United States. This communication is being distributed only to and is directed only at (a) persons outside the United Kingdom, (b) persons who have professional experience in matters relating to investments, i.e., investment professionals within the meaning of Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the “Order”), and (c) high net worth companies, unincorporated associations and other bodies to whom it may otherwise lawfully be communicated in accordance with Article 49 of the Order (all such persons together being referred to as “relevant persons”). The securities are available only to, and any invitation, offer or agreement to subscribe, purchase or otherwise acquire such securities will be available only to or will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this communication or any of its contents.
About Taj Pharmaceutical Limited

Taj Pharmaceuticals Limited is a pharmaceutical company founded and based in India. The company manufacturers pharmaceutical formulations and API for India and other countries of the world. The company was established in 1995 as an enterprise and in 2004 became a public limited company. As per Mumbai pharmacil and Chemixil association the company manufacturers and exports to countries like Albania, Argentina, Austria, Chile and Iraq. In 1995 pharmaceuticals wing only has a schedule M certification for pharmaceuticals products manufacturing in India. Taj Pharmaceuticals established its manufacturing unit in Gujarat because of government policies in 1999 with WHO / GMP licence. The company in 2003 revived all the old manufacturing units and approached the FDA Gujarat for 4000 new pharmaceuticals drug permissions for the first time in India.

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.

www.tajpharma.com

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