

10639-TESTOSTERONE BASE**1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.****1.1 Identification of the substance or preparation.**

Name: Testosterone Base

Bulk code: 10639

1.2 Synonyms.

No information available.

2. DESCRIPTION

Appearance: Crystalline powder or crystals.

Colour: White or almost white or colourless to white-yellowish.

Origin: Obtained from plant-based phytosterols (soya) and subsequent chemical handling so that they are identical to phytosterols of human origin.

Particle size: Micronised

3. COMPOSITION/INFORMATION ON COMPONENTS.Description: 17 β -Hydroxyandrost-4-en-3-one.Formula: C₁₉H₂₈NO₂

CAS No.: 58-22-0

Molecular weight: 288.4 g/mol

4. PHYSICO-CHEMICAL DATA.

See detailed specifications in analysis bulletin.

Solubility: Practically insoluble in water and fatty acids, soluble in alcohol and methylene chloride.**5. PROPERTIES/USES.**

ACTIVE PHARMACEUTICAL INGREDIENT.

Testosterone is the main androgenic hormone formed in the interstitial cells of the testicles or Leydig cells. Both testosterone and its esters have anabolic and androgenic properties. Testosterone is absorbed by the gastrointestinal tract, skin and oral mucosa. It is largely metabolised in the liver.

It can be administered transdermally to prolong its action.

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Testosterone esters are used in post-menopausal breast carcinoma, in certain post-menopausal disorders, such as osteoporosis, and to treat delayed puberty in males.

It is used in Hormone Replacement Therapy (HRT) as a bioidentical hormone to replace those hormones that the body needs to function properly.

6. DOSAGE.

Topical use:

- Usually: 120 mg oral dose three times a day at mealtimes, administered immediately before or up to 1 hour after meals.

If a meal is missed or contains no fat, the dose of orlistat should be omitted. If the patient does not lose at least 5% of their body weight during the first 12 weeks of treatment, treatment should be discontinued.

7. REMARKS.

STORAGE:

Store at room temperature ($25 \pm 2^\circ\text{C}$), in a cool, dry place, away from sunlight, in a tightly closed container.

8. BIBLIOGRAPHY.

European Pharmacopoeia.

"Martindale. The Extra Pharmacopoeia". 30th Edition. Ed. The Pharmaceutical Press. London. (1993).