

93521-TESTOSTERONE PROPIONATE**1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.****1.1 Identification of the substance or preparation**

Name: Testosterone Propionate

Bulk code: 93521

1.2 Synonyms

Testosteroni propionas.

2. DESCRIPTIONAppearance: **Powder or crystals.**

Colour: White or creamy white (powder) or colours, white or creamy white (crystals)

Smell: Odourless

Stable in air.

3. COMPOSITION/INFORMATION ON COMPONENTS.Formula: C₂₂H₃₂O₃

CAS: 57-85-2

Molecular weight: 344.5 g/mol

4. PHYSICO-CHEMICAL DATA.

See detailed specifications in analysis report.

Solubility: Practically insoluble in water, soluble in 3 p. alcohol, 4 p. acetone, 35 p. peanut oil, 20 p. ethyl oleate and 30 p. propylene glycol. Highly soluble in chloroform, dioxane, ether and ethyl alcohol; soluble in fixed oils.

Melting point: 119 – 123°C

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.

Topically, it is used in emulsions of an external aqueous phase to treat atopic skin processes, and in the form of an ointment on the male sex organs in cases with external expressions of hypogonadism and on the vulva in labial hypertrophy and other postmenopausal disorders.

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It is used as an adjuvant in postmenopausal breast carcinoma, some postmenopausal disorders and delayed puberty in children.

6. DOSAGE.

Topical use:

Emulsions: From 1 to 2.5%.

Ointments: Male hypogonadism up to 10% and labial hypertrophy at 2%.

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.

The product has been handled in a NON-sterile room; for batches suitable for sterile use, check availability.

8. BIBLIOGRAPHY.

Pharmaceutical Monographs. COF Alicante, 1998.

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