

Testosterone Enanthate (Cas No 315-37-7) Specification USP/BP

TAJCPG-DCYHEAPAZQ

Taj Active Pharmaceuticals Ingredients

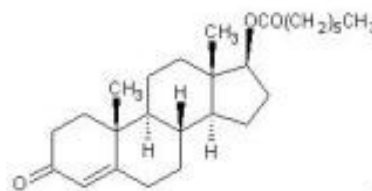
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Active Pharmaceutical Ingredients
TAJ PHARMACEUTICALS LIMITED INDIA



Raw Material / Chemicals Index

Taj Pharmaceuticals Ltd.
**Testosterone
Enanthate**
(CAS No.: 315-37-7)



Product Description

Product name	testosterone enanthate
Chemical name	4-Androsten-17β-ol-3-one Enanthate

CAS No.	315-37-7
Molecular formula	C ₂₆ H ₄₀ O ₃
Appearance	white crystalline powder or brown liquid.
Specification	USP/BP

Description:

Testosterone enanthate

is used in androgen substitution to replace testosterone at levels as close to physiological levels as is possible. For some androgen-dependent functions testosterone is a pro-hormone, peripherally converted to 5alpha-dihydrotestosterone (DHT) and 17beta-estradiol (E2), of which the levels preferably should be within normal physiological ranges. Furthermore, androgens should have a good safety profile without adverse effects on the prostate, serum lipids, liver or respiratory function, and they must be convenient to use and patient-friendly, with a relative independence from medical services. Natural testosterone is viewed as the best androgen for substitution in hypogonadal men. testosterone enanthate is used to treat male hypogonadism. Male hypogonadism is one of the most common endocrinologic syndromes. The diagnosis is based on clinical signs and symptoms plus laboratory confirmation via the measurement of low morning testosterone levels on two different occasions. Serum luteinizing hormone and follicle-stimulating hormone levels distinguish between primary (hypergonadotropic) and secondary (hypogonadotropic) hypogonadism. Osteoporosis in male hypogonadism: responses to androgen substitution differ among men with primary and secondary hypogonadism. In primary hypogonadal men the on bone mineral density (BMD) responds dose dependently to testosterone substitution, whereas in secondary hypogonadism only testosterone enanthate treatment significantly increased the BMD. In all mammalian species studied to date, testosterone has been found to be the predominant intratesticular steroid. In volunteers receiving hormonal contraception by using a combination of testosterone enanthate and levonorgestrel, there is a profound reduction of both intratesticular testosterone concentration and androgen bioactivity. High doses of testosterone enanthate can normalize hematocrit values of maintenance hemodialysis patients with replenished bone marrow iron stores. testosterone enanthate is classified as a prohibited substance by the World Anti-Doping Agency (WADA) and its use may be detected by way of the urinary testosterone/epitestosterone (T/E) ratio. (PMID: 16185098, 16467270, 15329035, 17530941, 17484401, 4028529, 12792150)

Testosterone enanthate Synonyms:

Testosterone Enanthate
 17β-Hydroxy-4-androsten-3-one 17-enanthate, 4-Androsten-17β-ol-3-one 17-enanthate, Testosterone 17β-heptanoate
 TESTOSTERONE ENANTHATE--DEA*SCHEDULE III
 testosterone entanoate
 17β-hydroxy-4-androsten-3-one 17-enanthate
 17b-hydroxyandrost-4-en-3-one-17-ethanate
 17BETA-HYDROXY-4-ANDROSTEN-3-ONE 17-ENANTHATE
 4-ANDROSTEN-17-BETA-OL-3-ONE ENANTHATE

Chemical IUPAC Name

[(8R,9S,10R,13S,14S,17S)-10,13-dimethyl-3-oxo-1,2,6,7,8,9,11,12,14,15,16,17-dodecahydrocyclopenta[a]phenanthren-17-yl] heptanoate

Chemical Taxonomy

Kingdom

* Organic

Super Class

* Cholesterols and derivatives

Class

* Steroids and Steroid Derivatives

Sub Class

* Ketosteroids

Family

* Mammalian Metabolite

Species

* ketone
* carboxylic acid ester
* alkene

Biofunction

* Hormones, Membrane component

Application

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Source

* Exogenous

Average Molecular Weight	400.594
Monoisotopic Molecular Weight	400.297760
Isomeric SMILES	<chem>CCCCCCC(=O)O[C@H]1CC[C@H]2[C@@H]3CCCC=CC(=O)CC[C@]4(C)[C@H]3CC[C@]12C</chem>
Canonical SMILES	<chem>CCCCCCC(=O)OC1CCC2C3CCC4=CC(=O)CCC4(C)C3CCC12C</chem>
InChI Identifier	InChI=1/C26H40O3/c1-4-5-6-7-8-24(28)29-23-12-11-21-20-10-9-18-17-19(27)13-15-25(18,2)22(20)14-16-/h17,20-23H,4-16H2,1-
	26(21,23)3 3H3/t20-,21-,22-,23-,25-,26-/m0/s1
Synthesis Reference	Ulrich, Miroslav; Novacek, Alois; Stejskal, Frantisek. Testosterone enanthate. (1960), CS 95825 55:81895 AN 1961:81895
	19600615 CAN
Melting Point (Experimental)	36-37.5 oC
Predicted Water Solubility	4.63e-04 mg/mL [Predicted by ALOGPS]; 5.43e-06 mg/mL at 25 oC [MEYLAN,WM et al. (1996)]
Physiological Charge	0
State	Solid
Predicted LogP/Hydrophobicity	5.11 [Predicted by ALOGPS]; 5.6 [Predicted by PubChem via XLOGP]; 6.73 [MEYLAN,WM & HOWARD,PH (1995)]
Fire and Explosion Data	
Flammability of the Product	May be combustible at high temperature.
Flash Points	CLOSED CUP: Higher than 93.3°C (200°F).
Products of Combustion	These products are carbon oxides (CO, CO2).
Fire Hazards in Presence of Various Substances	Slightly flammable to flammable in presence of heat. Non-flammable in presence of shocks.
Explosion Hazards in Presence of Various Substances	Slightly explosive in presence of open flames and sparks. Non-explosive in presence of shocks.
Fire Fighting Media	SMALL FIRE: Use DRY chemical powder.

and Instructions

LARGE FIRE: Use water spray, fog or foam. Do not use water jet.

Special Remarks on Hazards

As with most organic solids, fire is possible at elevated Fire temperatures

Special Remarks on Explosion Hazards

Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Accidental Release Measures**Small Spill**

Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

Large Spill

Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

Handling and Storage**Precautions**

Keep away from heat. Keep away from sources of ignition. Ground all equipment containing material. Do not ingest. Do not breathe dust. Wear suitable protective clothing. If ingested, seek medical advice immediately and show the container or the label. Keep away from incompatibles such as oxidizing agents.

Storage

Keep container tightly closed. Keep container in a cool, well-ventilated area. Sensitive to light. Store in light-resistant containers. Refrigerate

Exposure Controls/Personal Protection**Engineering Controls**

Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protection

Splash goggles. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.

Personal Protection in Case of a Large Spill

Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Physical and Chemical Properties

Physical state and appearance Solid. (Crystalline solid. Powdered solid.)

Molecular Weight 400.59 g/mole

Melting Point 34°C (93.2°F) - 39 C.

Solubility

Insoluble in cold water, hot water. Soluble in chloroform.

Stability and Reactivity Data

Stability The product is stable.

Conditions of Instability Excess heat, incompatible materials

Incompatibility with various substances Reactive with oxidizing agents.

Testosterone Enanthate

Special Remarks on Reactivity Sensitive to light.

Polymerization Will not occur.

Toxicological Information

Routes of Entry Absorbed through skin. Inhalation. Ingestion.

Toxicity to Animals Acute oral toxicity (LD50): >1000 mg/kg [Rat].

Chronic Effects on Humans

TERATOGENIC EFFECTS: Classified POSSIBLE for human.

DEVELOPMENTAL TOXICITY: Classified Reproductive system/toxin/female, Reproductive system/toxin/male [POSSIBLE].

May cause damage to the following organs: blood, the reproductive system, liver.

Other Toxic Effects on Humans

Slightly hazardous in case of skin contact (irritant, permeator), of ingestion, of inhalation.

Special Remarks on Chronic Effects on Humans

May affect genetic material (mutagenic).

May cause adverse reproductive effects and birth defects (teratogenic).

May cause cancer

Ecological Information

Products of Biodegradation

Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation

The products of degradation are less toxic than the product itself.

Waste Disposal

Waste must be disposed of in accordance with federal, state and local environmental control regulations.

Other Regulations

OSHA: Hazardous by definition of Hazard Communication Standard (29 CFR 1910.1200). EINECS: This product is on the European Inventory of Existing Commercial Chemical Substances.

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