Jatenzo (testosterone undecanoate)

NEW PRODUCT SLIDESHOW

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Introduction

- **Brand name:** Jatenzo
- **Generic name:** Testosterone undecanoate
- **Pharmacologic class:** Androgen
- **Strength and Formulation:** 158mg, 198mg, 237mg; gel capsules; contains castor oil
- **Manufacturer:** Clarus Therapeutics
- **How supplied:** Bottles—120
- **Legal Classification:** CIII

Jatenzo


NDC 69087-237-12
JATENZO®
(testosterone undecanoate)
Capsules
237 mg
Rx Only
120 Soft Gelatin Capsules
clarus
THERAPEUTICS
237

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Indication

- For **testosterone replacement therapy** in adult males for conditions associated with a deficiency or absence of endogenous testosterone:
  - *Primary hypogonadism (congenital or acquired)*: testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter syndrome, chemotherapy, or toxic damage from alcohol or heavy metals (usually low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range)
  - *Hypogonadotropic hypogonadism (congenital or acquired):* gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation (low testosterone serum concentrations but gonadotropins in normal or low range)

Limitations of Use

- Safety and efficacy in males <18 years old: not established

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Dosage and Administration

- Prior to treatment, confirm diagnosis by ensuring serum testosterone has been measured in the AM on at least 2 separate days and that these concentrations are below normal range
- Individualize dose
- Take with food
- **≥18yrs**: initially 237mg twice daily (AM + PM); max 396mg twice daily

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Dose Adjustment Scheme

Testosterone Concentration in Serum From Plain Tube Drawn 6 hours After Morning Dose	Current Jatenzo Dose (mg, twice daily)	New Jatenzo Dose (mg, twice daily)
<425ng/dL	158	198
	198	237
	237	316 (two 158mg caps)
	316 (two 158mg caps)	396 (two 198mg caps)
425ng/dL-970ng/dL	No change	No change
>970ng/dL	396 (two 198mg caps)	316 (two 158mg caps)
	316 (two 158mg caps)	237
	237	198
	198	158
	158	Discontinue treatment

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Considerations for Special Populations

- **Pregnancy:** contraindicated; teratogenic
- **Male reproductive potential**: may suppress spermatogenesis; reduced fertility has been observed with testosterone replacement therapy
- **Pediatric**: safety and effectiveness not established in patients <18 years old
- **Geriatric:** studies did not include sufficient number of patients >65 years; may be at increased risk for worsening BPH

Contraindications

- Male breast or prostate cancer
- Age-related hypogonadism
- Pregnancy

Boxed Warning

- May cause **blood pressure (BP) increases** that may increase risk of major adverse cardiovascular events (MACE)
- Before initiating, consider baseline cardiovascular (CV) risk and ensure BP adequately controlled
- Starting approx. 3 weeks after initiating or changing dose, periodically monitor for and treat new-onset hypertension or exacerbations of preexisting hypertension
- Reevaluate whether benefits outweigh risks in those who develop CV risk factors or CVD

Warnings/Precautions

- Not for use in women
- Increases in BP (see **Boxed Warning**)
- Monitor hematocrit prior to initiation and approx. every 3 months during treatment; if elevation occurs, withhold until acceptable level
- Increased risk of worsening BPH; monitor
- Evaluate for prostate cancer prior to and during treatment
- Monitor for venous thromboembolism; discontinue if suspected
- Preexisting cardiac, renal or hepatic disease (discontinue if edema occurs)

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Warnings/Precautions

- Discontinue and evaluate if signs/symptoms of hepatic dysfunction (eg, jaundice) occur
- Possible sleep apnea in patients with obesity or chronic lung disease
- Testosterone and/or other anabolic androgenic steroid abuse
- Monitor serum testosterone, PSA, liver function, lipid profile, serum calcium (in cancer patients at risk for hypercalcemia/hypercalciuria) periodically
- Risk of depression, suicidal ideation

Interactions

- May alter insulin sensitivity and glycemic control; reduce dose of antidiabetic agents if needed
- Increased fluid retention with concomitant corticosteroids; monitor
- Monitor INR and PT with concomitant oral anticoagulants
- Concomitant prescription or OTC analgesic and cold medications may lead to additional BP increases
- May alter serum lipids; adjust dose of lipid-lowering drugs or discontinue testosterone
- May affect thyroid levels

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Adverse Reactions

- **Most common (incidence >2%)**: polycythemia, diarrhea, dyspepsia, eructation, peripheral edema, nausea, increased hematocrit, headache, prostatomegaly, hypertension

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Clinical Trials

- Efficacy and safety evaluated in 166 adult hypogonadal males in an open-label study of approximately 4 months duration
- Study included a screening phase, a treatment titration phase, and a treatment maintenance phase
- Jatenzo was taken orally at a starting dose of 237mg twice per day with meals
- Dose was adjusted on Days 21 and 56 between a minimum of 158mg twice per day and a maximum of 396mg twice per day on the basis of average testosterone concentration obtained over 24 hours post-morning dose

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Clinical Trials

- **Primary end point**: percentage of patients with mean plasma total testosterone concentration over 24-hours within the normal eugonadal range on the final PK visit of the study

- **Secondary end points**: percentage of patients with a maximum total testosterone concentration (C_{max}) above 3 predetermined limits: less than or equal to 1500ng/dL, between 1800 and 2500ng/dL, and greater than 2500ng/dL

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Clinical Trials

- 145 (87%) of 166 hypogonadal men who received Jatenzo had mean total testosterone concentration within normal eugonadal range at end of treatment

- Percentage of patients who received Jatenzo and had C_{max} less than or equal to 1500ng/dL, between 1800 and 2500ng/dL, and greater than 2500ng/dL at the final PK visit were 83%, 3%, and 3%, respectively

New Product Monograph

- For more information view the product monograph available at:

  https://www.empr.com/drug/jatenzo/