KYZATREX®

Lab Timing Troubleshooting Guide

KYZATREX® (testosterone undecanoate) capsules, CIII

TESTOSTERONE UNDECANOATE CAPSULES

KYZATREX (testosterone undecanoate) capsules, CIII, is indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Safety and efficacy of KYZATREX in males less than 18 years old have not been established. Safety and efficacy of KYZATREX in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.

Not actual size.

Key Troubleshooting Questions to Ask

Accurate labs are essential for evaluating your patients' response to KYZATREX, but timing and proper administration are critical in achieving reliable results. If your patient's testosterone labs aren't aligning with expectations, here's what to check:

1 Did the Patient Take the Dose Correctly?

KYZATREX should be taken **twice daily with food** as recommended. Food enhances absorption and ensures consistent testosterone levels.

2 Were Labs Drawn at the Correct Time?

Labs should be drawn **3–5 hours after the morning dose** to align with KYZATREX's pharmacokinetic profile.

3 Is the Patient Consistent with Twice-daily Dosing?

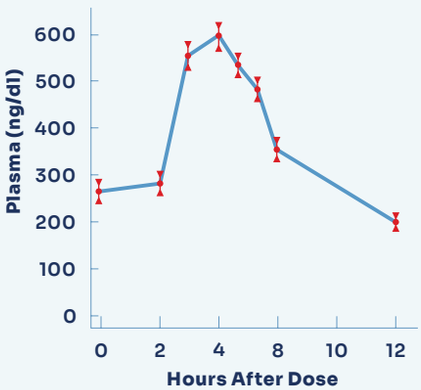
Missing or **delaying doses** can lead to suboptimal testosterone levels and inaccurate lab readings.

4 How is the Patient Responding?

Evaluating any improvement in the patient's symptoms can provide valuable insights into the efficacy of treatment.

KYZATREX's PK Profile[1-3]

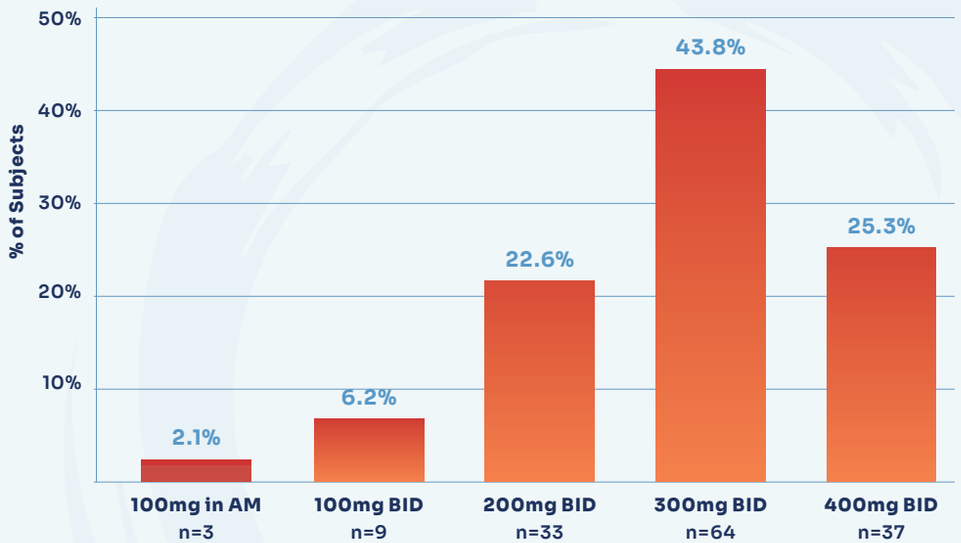
KYZATREX delivers reliable testosterone support between doses, **maintaining balance without extreme highs and lows.**



Primary Dose Distribution[3]

KYZATREX Final Dose at Day 90 (MRS-TU-2019EXT)

All KYZATREX patients received a starting dose of 200mg twice daily with meals. Dosage was adjusted on Days 28 and 56.



Check hematocrit prior to initiation and every 3 months during treatment to detect increased red blood cell mass and polycythemia. If hematocrit becomes elevated, stop KYZATREX until the hematocrit decreases to an acceptable level. If hematocrit increases after KYZATREX is restarted, permanently discontinue treatment.

Please see additional Important Safety Information on back and accompanying Full Prescribing Information.

INDICATION

KYZATREX® (testosterone undecanoate) capsules, CIII, is indicated 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 conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have 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, pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low serum testosterone concentrations but have gonadotropins in the normal or low range.

Limitations of Use

- Safety and efficacy of KYZATREX® in males less than 18 years old have not been established.
- Safety and efficacy of KYZATREX® in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.

IMPORTANT SAFETY INFORMATION FOR KYZATREX® (testosterone undecanoate)

Contraindications

KYZATREX® is contraindicated in patients with carcinoma of the breast or known or suspected carcinoma of the prostate; women who are pregnant (testosterone may cause fetal harm); and patients with known hypersensitivity to KYZATREX® or any of its ingredients.

Warnings and Precautions

Polycythemia. Check hematocrit prior to initiation and every 3 months during treatment to detect increased red blood cell mass and polycythemia. If hematocrit becomes elevated, stop KYZATREX® until the hematocrit decreases to an acceptable level. If hematocrit increases after KYZATREX® is restarted, permanently discontinue treatment.

Venous Thromboembolism (VTE). VTE, including deep vein thrombosis (DVT) and pulmonary embolism (PE), have been reported in patients using testosterone products. Evaluate patients who report symptoms of pain, edema, warmth, and erythema in the lower extremity for DVT and those who present with acute shortness of breath for PE. Discontinue KYZATREX® if VTE is suspected and initiate appropriate workup and management.

Worsening of Benign Prostatic Hyperplasia (BPH) and Potential Risk of Prostate Cancer.

Monitor patients for worsening of signs and symptoms of BPH. Evaluate patients for prostate cancer prior to initiating and during treatment with androgens.

Blood Pressure (BP) Increases. KYZATREX® can increase blood pressure. Blood pressure increases can increase cardiovascular (CV) risk over time. Monitor BP periodically in men using KYZATREX®, especially men with hypertension. KYZATREX® is not recommended for use in patients with uncontrolled hypertension.

Abuse of Testosterone and Monitoring of Testosterone Concentrations. Testosterone has been subject to abuse, typically at doses higher than indicated and in combination with other anabolic androgenic steroids. If abuse is suspected, check testosterone levels to ensure they are within therapeutic range. Counsel patients concerning the serious adverse reactions associated with abuse and consider the possibility of abuse in suspected patients who present with serious cardiovascular or psychiatric adverse events.

Not for Use in Women. Due to lack of controlled studies in women and potential virilizing effects, KYZATREX® is not indicated for use in women.

Potential for Adverse Effects on Spermatogenesis. Large doses of androgens can suppress spermatogenesis. Inform patients of this risk before prescribing KYZATREX®.

Hepatic Adverse Effects. KYZATREX® is not a 17-alpha-alkyl androgen and is not known to cause hepatic adverse effects. However, patients should be instructed to report any signs or symptoms of hepatic dysfunction (e.g., jaundice). If these occur, promptly discontinue KYZATREX® while the cause is evaluated.

Edema. Edema may occur in patients with pre-existing cardiac, renal, or hepatic disease. In addition to discontinuing KYZATREX®, diuretic therapy may be required.

Sleep Apnea. KYZATREX® may potentiate sleep apnea in some patients, especially those with risk factors such as obesity or chronic lung disease.

Lipid Changes. KYZATREX® may affect serum lipid profiles. Monitor patient lipid concentrations periodically; if necessary, adjust dosage of lipid lowering drug(s) or discontinue KYZATREX®.

Other warnings include: gynecomastia; hypercalcemia in cancer patients; and decreased thyroxine-binding globulin.

Adverse Events

The most common adverse reaction of KYZATREX® (incidence ≥ 2%) is hypertension (2.6%).

Drug Interactions

Insulin. KYZATREX® can cause changes in insulin sensitivity or glycemic control. Androgens may decrease blood glucose requiring a decrease in the dose of anti-diabetic medication.

Oral Vitamin K Antagonist Anticoagulants. Anticoagulant activity may be seen with androgens. More frequent monitoring of international normalized ratio (INR) and prothrombin time are recommended in patients taking warfarin, especially at initiation and termination of androgen therapy.

Corticosteroids. Concurrent use of testosterone with corticosteroids may increase fluid retention and requires careful monitoring, particularly in patients with cardiac, renal, or hepatic disease.

Medications that May Also Increase Blood Pressure. Concomitant administration of medications drugs known to increase BP with KYZATREX® may lead to additional BP increases.

Use in Specific Populations

Females. KYZATREX® is contraindicated in pregnant women and is not indicated for use in females.

Pediatric Use. The safety and efficacy of KYZATREX® in pediatric patients less than 18 years old have not been established. Use in pediatric patients may result in acceleration of bone age and premature closure of epiphyses.

Geriatric Use. KYZATREX® clinical studies did not include patients ≥65 years. It is unknown whether these patients respond differently from younger adult patients or have an increased risk of cardiovascular disease and prostate cancer. Geriatric patients treated with androgens may be at risk for worsening of signs and symptoms of BPH.

Dosage and Administration

KYZATREX® is not substitutable with other oral testosterone undecanoate products. Prior to initiating KYZATREX®, confirm the diagnosis of hypogonadism by ensuring that serum testosterone concentrations have been measured in the morning on at least two separate days and that these testosterone concentrations are below the normal range.

Please note that this information is not comprehensive. Please visit www.kyzatrex.com or scan QR code below for Full Prescribing Information, including Patient Medication Guide.

To report SUSPECTED ADVERSE REACTIONS, contact Marius Pharmaceuticals at 1-833-949-5040 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

References:

1. Bernstein JS. Dhingra OP. A phase III, single-arm, 6-month trial of a wide-dose range oral testosterone undecanoate product. *Ther Adv Urol*. 2024;16:1-17. doi: 10.177/17562872241241864
2. KYZATREX [prescribing information]. Raleigh, NC: Marius Pharmaceuticals; 2025.
3. Data on file. Raleigh, NC: Marius Pharmaceuticals, 2020.

Please scan for Full Prescribing Information, including Patient Medication Guide.

MARIUS pharmaceuticals

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