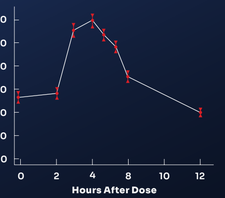
Optimized for Lymphatic Uptake

KYZATREX utilizes a **Self-Emulsifying Drug Delivery System** (SEDDS) enhanced with **phytosterol esters** to route testosterone undecanoate (TU) through the intestinal lymphatic system, **bypassing the liver and avoiding first-pass metabolism.**[4,5]

A Broad PK Profile Without Extreme Peaks and Troughs[4,6,7]

KYZATREX is designed to restore and maintain testosterone levels in a physiologic pattern following each dose.



Mean plasma T values:[4,6,7]

C_{max} = 852.4 ng/dL
C_{min} = 161.6 ng/dL
C_{avg} = 393.3 ng/dL

Plasma peak-to-trough ratio: 5.5*

Serum T values:[4,6,7]

C_{max} = 970.1 ng/dL
C_{min} = 186.6 ng/dL
C_{avg} = 451.9 ng/dL

Serum peak to-trough ratio: 5.2*

*Geometric Means Calculation

KYZATREX safely restores T levels while allowing the hypothalamic-pituitary-gonadal (HPG) axis to remain active. T levels return to near baseline between KYZATREX doses, maintaining HPG axis function.[6]

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.

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

Safety

Blood Pressure Endpoint
Phase 3 Study: MRS-TU-2019EXT (N=155)

ABPM[4,6]

Change in 24-hour mean SBP from baseline after **4 months** of KYZATREX, mmHg (95% CI)	**1.7** (0.3-3.1)
Change in 24-hour mean SBP from baseline after **6 months** of KYZATREX, mmHg (95% CI)	**1.8** (0.3-3.2)

ABPM, ambulatory blood pressure monitoring;
CI, confidence interval; **SBP**, systolic blood pressure.

Adverse Events in ≥2% of Patients Receiving KYZATREX[6]

Adverse Reaction (N=155)	**n (%)**
Hypertension*	4 (2.6)

*Based on blood pressure cuff measurements

One patient who received KYZATREX experienced an adverse reaction (acne) that led to premature discontinuation from the study.[5]
No patients withdrew due to erythrocytosis.[5]

Blood Parameters[4,6,7] (Mean change from baseline at 6 months)

PSA	↑ 0.15 (±0.04) ng/mL
Hemoglobin	↑ 0.48 g/dL Levels plateaued after 90 days of treatment
Total Cholesterol	↓ 11.1 mg/dL
Triglycerides	↓ 18.6 mg/dL
Fasting Insulin†	↓ 5.2 µU/mL

† Data from MRS-TU-2019 (n=153) at 12 months. Fasting insulin was an exploratory endpoint; this study was not designed or statistically powered to demonstrate differences in exploratory endpoints. MRS-TU-2019 had a different dosing scheme from MRS-TU-2019EXT.

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

Not actual size. Also available in 100 and 150 mg

Not actual size. Also available in 100 and 150 mg

Why Your Patients May Choose KYZATREX

	KYZATREX®	Injections	Pellets	Gels
Oral Capsule	✓	✗	✗	✗
Discreet	✓	✓	✓	✓
No Mess	✓	✓	✓	✗
Painless	✓	✗	✗	✓
Flexible Dosing	✓	✓	✓	✓

KYZATREX Patient Type Considerations

KYZATREX might be suitable for your patient if they meet the diagnosis criteria and:

- This is their first time pursuing TRT.
- They prefer not to use needles.[4, 5]
- They are worried about transferring gel medication to loved ones.[4, 5]
- They are an existing TRT patient who is tired of donating blood due to high levels of hematocrit.

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 the back and accompanying Full Prescribing Information.

Not actual size. Also available in 100 and 150 mg

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 see accompanying 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. Li Y, Liu M, Cui Y, et al. Increased risk of testosterone deficiency is associated with the systemic immune-inflammation index: a population-based cohort study. *Front Endocrinol.* 2022; 13:975773. doi: 10.3389/fendo.2022.975773
2. National Population by Characteristics: 2020-2022. Annual Estimates of the Resident Population for Selected Age Groups by Sex for the United States: April 1, 2020 to July 1, 2023 (NC-EST2022-SYAEXN). U.S. Census Bureau. https://www.census.gov/data/tables/time-series/demo/popest/2020s-national-detail.html. Accessed September 11, 2023.
3. Travison TG, Araujo AB, O'Donnell AB, et al. A Population-Level Decline in Serum Testosterone Levels in American Men. *J Clin Endocrinol Metab.* January 2007, 92(1):196–202.
4. 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: 10.1177/17562872241421854
5. Kanabur P, Brunner R, Khera D, et al. The Evolving Role of Novel Oral Agents for Testosterone Replacement Therapy: A Historical Perspective. *Advog Clin Res Ther.* 2022;3.1:224-232. doi: 10.1089/andro.2021.0025
6. KYZATREX [prescribing information]. Raleigh, NC: Marius Pharmaceuticals; 2025.
7. Data on file. Raleigh, NC: Marius Pharmaceuticals, 2020.
8. Data on file. Raleigh, NC: Marius Pharmaceuticals, 2018.

MARIUS pharmaceuticals

Marius Pharmaceuticals
2301 Sugar Bush Road, Suite 510 Raleigh, NC 27612 | kyz-0101-0037 | Rev. 1 | Exp. 10/2026

919-374-1913
mariuspharma.com

Full Prescribing Information

Medication Guide

KYZATREX®

TESTOSTERONE UNDECANOATE CAPSULES

HELP YOUR PATIENTS GET BACK IN RANGE

KYZATREX®

FDA-Approved Oral Testosterone Replacement Therapy

Actor Portrayal

A good choice for your patients.
A good decision for your practice.

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.

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

The Big Need for Testosterone Replacement Therapy (TRT)

Low T Affects an Estimated **20 Million Men** from Ages 20-65 in the U.S.[1,2]

Help Your Patients Address the Decline in Testosterone Levels

Men born in more recent years have lower testosterone levels than previous generations, with average levels declining by about 1% per year since 1987.[3]

Healthcare providers like you are on the frontlines of this men's health crisis. Talk to your patients about the prevalence of hypogonadism, and be part of the solution with testosterone replacement therapy.

Not Actual Size

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

Clinically Restore Testosterone Levels

Up to **96% of Patients** Achieved Normal T Levels at Day 90[4,6*]

*In a six-month clinical trial of 139 men with low testosterone, 88% of patients had normal testosterone levels at Day 90 (worst-case scenario calculation, excluding Investigator Site 104). Based on patients who completed the study (n=127), 96% of patients achieved normal testosterone levels at Day 90.

2x Increase in Mean Free Testosterone Levels[4]

30% Decrease in Mean Sex Hormone Binding Globulin Levels[7]

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

Not Actual Size

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

Not actual size. Also available in 100 and 150mg

Not actual size. Also available in 100 and 150 mg

KYZATREX Daily Oral Dosing

An Oral Testosterone Treatment Designed to Fit into Your Patients' Lives

Twice a day with food[6]	No changes to diet or eating habits needed[6]	Can be taken with alcohol[6]	Easy for travel

Dosing Flexibility

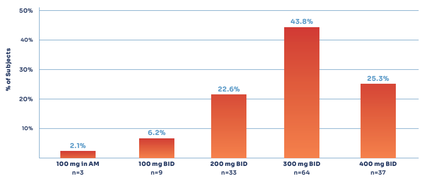
Not Actual Size

Recommended Starting Dose[6]

200 mg twice daily (400 mg total daily dose)

Dosing may be adjusted depending on how your patient responds to KYZATREX.

Primary Dose Distribution
KYZATREX Final Dose at Day 90 (MRS-TU-2019EXT)[7]



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Provider and Patient Preference for Oral Testosterone[8]

89% **of HCPs somewhat or strongly prefer KYZATREX to injectables***

*2018 quantitative study of 78 Primary Care Physicians, Endocrinologists and Urologists

76% **of current TRT users said they would likely switch to an oral option if provided****

**2018 quantitative study of 83 hypogonadal patients; TRT users (n=49), Non-TRT users (n=34)

Patient Testimonials

"I have recently taken my health into my own hands after my labs reflected low testosterone. I have been on KYZATREX for more than 4 months now and my testosterone levels are back to normal. My life has changed for the better. I really do attribute this jumpstart in health to KYZATREX."
Bryan N, 56

"When I first discovered I had Low T, I went with pellet therapy. While pellets seemed fine at first, they eventually became too much of a hassle – the painful implant process, scar tissue buildup and activity restrictions just weren't for me, especially when the effects started wearing off before the next dose. As soon as I heard there was an oral option, that's when I switched to KYZATREX. I love the convenience of the capsules, and my testosterone levels are in the normal range! It's made a real difference in how I feel."
David W, 41

"For years I used testosterone injections but wanted to switch to an oral TRT. My doctor recommended KYZATREX due to its tolerability and side effect profile and I've now been on KYZATREX for 8 months. My testosterone levels are about 700 ng/dL and I feel just as good, if not better, on KYZATREX than I did on injections."
Brian R, 47

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.

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Discover the Difference KYZATREX Can Make in Managing Low Testosterone

Cash-Only Model

- Eliminates the need for prior authorizations
- No insurance hassles
- Simplifies the prescribing process for both providers and patients

Cost Predictability

- Transparent pricing ensures patients know their out-of-pocket expenses upfront
- Avoids unexpected costs and insurance-related delays

Patient Convenience

- Oral administration means no need for frequent in-office visits for injections
- Capsule formulation allows patients to integrate treatment into their daily routines.

To learn more about KYZATREX, visit **www.kyzatrex.com/prescriber** or scan the QR code to request a meeting with one of our dedicated sales representatives.

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.

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