



@ TESTOSTERONE UNDECANOATE CAPSULES



Your Role in Successful Treatment



Monitoring: Keep regular appointments and follow your doctor's advice for blood tests to monitor your testosterone levels and overall health.



Communication: Discuss any concerns or side effects with your healthcare provider.



Adherence to Medication: Take KYZATREX exactly as prescribed, twice daily with meals.

For More Information

Visit www.kyzatrex.com or talk to your healthcare provider about any questions or further information on KYZATREX and your testosterone replacement therapy.

What is KYZATREX®

KYZATREX® (testosterone undecanoate) is a prescription drug that is used to treat adult men who have low or no testosterone levels due to certain medical conditions.

KYZATREX® is a controlled substance (CIII) because it contains testosterone.

It is not known if KYZATREX® is safe or effective in males younger than 18 years old. Improper use may affect bone growth in children.

It is not known if KYZATREX® is safe or effective in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism").

KYZATREX® is not meant for use by women.

Important Safety Information for KYZATREX®

Do not take KYZATREX® if you: have breast cancer; have or might have prostate cancer; are a woman who is pregnant (KYZATREX® may harm your unborn baby); or are allergic to KYZATREX® or any of its ingredients.

Before you take KYZATREX®, tell your healthcare provider about all of your medical conditions, including if you: have high blood pressure or are treated for high blood pressure; have a history of diabetes; have heart problems; have high red blood cell count (hematocrit) or high hemoglobin laboratory value; have urinary problems due to an enlarged prostate; have liver or kidney problems; or have problems breathing while you sleep (sleep apnea).

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking KYZATREX® with certain other medicines can affect each other. **Especially, tell your healthcare provider if you take:** insulin; medicines that decrease blood clotting (blood thinners); corticosteroids; or medicines that increase blood pressure, such as some cold medicine and pain medicines.

KYZATREX® may cause other serious side effects including:

- **Increase in red blood cell count (hematocrit) or hemoglobin**, which can increase the risk of blood clots, strokes, and heart attacks. You may need to stop KYZATREX® if your red blood cell count increases.
- **If you already have an enlarged prostate, your signs and symptoms may worsen while taking KYZATREX®.** These may include: increased urination at night; trouble starting your urine stream; urinating many times during the day; urge to go to the bathroom right away; a urine accident; inability to pass urine or weak urine flow.
- **Increased risk of prostate cancer.**
- **Blood clots in the legs or lungs.** Signs and symptoms of a blood clot in your leg can include pain, swelling or redness. Signs and symptoms of a blood clot in your lungs can include difficulty breathing or chest pain.
- **Abuse.** Testosterone can be abused when taken at higher than prescribed doses and when used with other anabolic androgenic steroids.

Abuse can cause serious heart and psychological side effects.

- **In large doses, KYZATREX® may lower your sperm count.**
- **Liver problems.** Symptoms of liver problems may include: nausea or vomiting; yellowing of your skin or whites of your eyes; dark urine; pain on the right side of your stomach area (abdominal pain).
- **Swelling of your ankles, feet, or body (edema), with or without heart failure.**
- **Enlarged or painful breasts.**
- **Breathing problems while you sleep (sleep apnea).**

Call your healthcare provider right away if you have any of the serious side effects listed above.

The most common side effect of KYZATREX® is high blood pressure. Other side effects may include: headache, joint or back pain, diarrhea, increased red blood cell count, anxiety, constipation, swelling of the legs, and increased prostate specific antigen (PSA) levels.

These are not all the possible side effects of KYZATREX®. For more information, ask your healthcare provider or pharmacist.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088. You may also report side effects to Marius by visiting www.mariuspharma.com.

Keep KYZATREX® and all medicines out of the reach of children.

See Full Prescribing Information and Medication Guide for KYZATREX® at www.kyzatrex.com.

References:

1. Krakowsky Y, Grober E. Testosterone deficiency – Establishing a Biochemical Diagnosis. *EJIFCC*. 2015 Mar; 26(2): 105–113. PMID: 27683486; PMCID: PMC4975356.
2. Bernstein JS, Dhirga OP. A phase III, single-arm, 6-month trial of a wide-dose range oral testosterone undecanoate product. *Ther Adv Urol*. 2024;16:17562872241241864. Published 2024 Apr 10. doi:10.1177/17562872241241864



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What to Expect

Starting Treatment with Twice-daily, FDA-approved KYZATREX®

KYZATREX is a prescription oral testosterone treatment for adult men who have low or no testosterone levels due to certain medical conditions. KYZATREX is a controlled substance (CIII) because it contains testosterone. It is not known if KYZATREX is safe or effective in males younger than 18 years old. Improper use may affect bone growth in children. It is not known if KYZATREX is safe or effective in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism").



No Administration Pain

No Mess

No Transference Risk

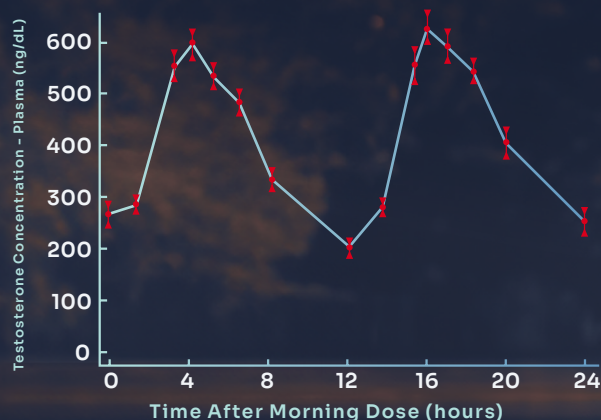
Please see additional Important Safety Information on back.

Expectations with KYZATREX

For Patients Transitioning from Other Forms of TRT

If you're used to treatments like injections, you may notice that KYZATREX doesn't cause you to feel huge spikes in energy and performance. Instead, KYZATREX focuses on maintaining your testosterone within a range that is considered medically normal without unnatural highs or extreme lows.

Mean (Standard Error of the Mean)
Testosterone Concentration (ng/dL)
Post Morning KYZATREX Dose at Day 90



KYZATREX is an immediate-release formulation with twice-daily dosing that, when taken every 12 hours with food, closely mimics the body's natural daily rhythm of testosterone production.

Why Not Super High Levels?

KYZATREX is an immediate-release formulation that raises testosterone levels each time you take it (2 times per day). After each dose, your testosterone levels slowly decline before your next dose. KYZATREX focuses on maintaining your testosterone within a range that is medically considered normal and sufficient.

Do not take KYZATREX if you: have breast cancer; have or might have prostate cancer; are a woman who is pregnant (KYZATREX may harm your unborn baby); or are allergic to KYZATREX or any of its ingredients.



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For New TRT Patients

Testosterone levels begin to normalize following the first dose. If KYZATREX works correctly for you, your levels should rise to within the normal range within a week.

Side Effects

The most common side effect reported with KYZATREX is an increase in blood pressure, observed in 2.6% of patients. Your healthcare provider will monitor your blood pressure while you are being treated with KYZATREX.



KYZATREX may cause serious side effects, including an increase in red blood cell count (hematocrit) or hemoglobin, which can increase the risk of blood clots, strokes, and heart attacks. You may need to stop KYZATREX if your red blood cell count increases. Other side effects may include: headache, joint or back pain, diarrhea, increased red blood cell count, anxiety, constipation, swelling of the legs, and increased prostate specific antigen (PSA) levels.

Please see additional Important Safety Information on back.

Total Testosterone vs. Free Testosterone

Your body has two forms of testosterone:

Total Testosterone (Total T)

This includes **all testosterone in your blood**, both free and bound to proteins.

Free Testosterone (Free T)

This is the testosterone that is freely circulating and available for immediate use. Free T is crucial because it represents the **active portion that your body uses to do its job.**¹

The Role of Sex Hormone Binding Globulin

Sex Hormone Binding Globulin (SHBG) is a protein that binds to testosterone, making it unavailable for use. **High levels of SHBG can lower Free T levels.**¹

KYZATREX has been shown to decrease SHBG levels and inversely increase levels of Free T.²



Important Safety Information for KYZATREX (cont'd)

Before you take KYZATREX, tell your healthcare provider about all of your medical conditions, including if you: have high blood pressure or are treated for high blood pressure; have a history of diabetes; have heart problems; have high red blood cell count (hematocrit) or high hemoglobin laboratory value; have urinary problems due to an enlarged prostate; have liver or kidney problems; or have problems breathing while you sleep (sleep apnea).