



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. They are there to ensure your treatment is both effective and safe.



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.

IMPORTANT SAFETY INFORMATION

Use

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. KYZATREX is not meant for use by women.

Important Safety Information For KYZATREX®

KYZATREX can increase blood pressure, which can increase the risk of having a heart attack or stroke and can increase risk of death due to a heart attack or stroke. Your risk may be greater if you have already had a heart attack or stroke or if you have other risk factors for heart attack or stroke.

- If your blood pressure increases while on KYZATREX, blood pressure medicines may need to be started. If you are currently taking blood pressure medicines, they may need to be changed or new blood pressure medicines may need to be added to control your blood pressure.
- If your blood pressure cannot be controlled, KYZATREX may need to be stopped.
- Your healthcare provider will monitor your blood pressure while you are being treated with 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); are allergic to KYZATREX or any of its ingredients; or have low testosterone without certain medical conditions (e.g., do not take KYZATREX if you have low testosterone due to age).

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 cause adverse effects. **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 medicines 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.



Marius Pharmaceuticals
2301 Sugar Bush Road, Suite 510
Raleigh, NC 27612

919-374-1913 | mariuspharma.com
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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 helps restore testosterone to normal levels, offering stable results from a capsule.



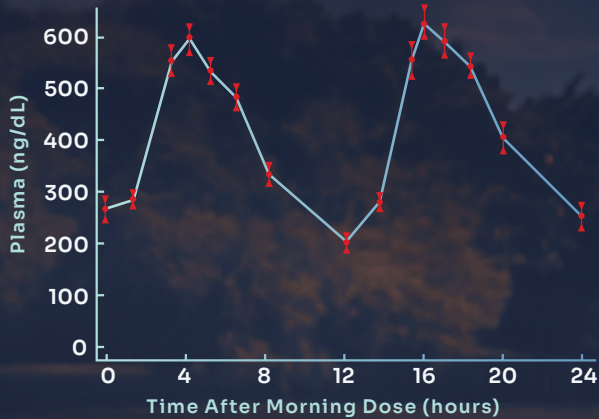
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Please see additional Important Safety Information, including Boxed Warning, on back.

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 maintains more natural, stable levels throughout the day and night, closely mimicking the way your body naturally produces testosterone.



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?

While you might read about high testosterone levels achieved with injectables, such high levels are not necessarily better for health and can lead to unwanted side effects. KYZATREX focuses on maintaining your testosterone within a range that is medically considered normal and sufficient to alleviate the symptoms of low testosterone.



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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.

Important Safety Information for KYZATREX (cont'd)

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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.

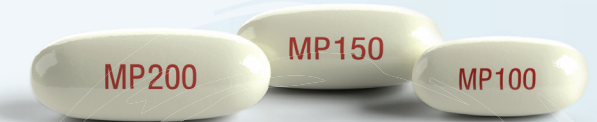
Free Testosterone (Free T)

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 can utilize** for various functions, from muscle building to mood regulation.

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.**

KYZATREX has been shown to decrease SHBG levels and inversely **increase levels of Free T** - the active form of testosterone your body can use.



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