



KYZATREX® (testosterone undecanoate) CIII Capsules EXPANDS DISTRIBUTION THROUGH NEW COLLABORATION WITH GAMEDAY MEN'S HEALTH

The Deal Gives Gameday Men's Health Patients Access to The FDA-Approved Oral Testosterone Therapy At 250+ Health Centers



Raleigh, NC (November X, 2024) — [Gameday Men's Health](#), the leader in men's health clinics nationwide, today announced it is expanding its testosterone therapy options to include [KYZATREX®](#) (testosterone undecanoate) CIII capsules. Partnering with [Marius Pharmaceuticals](#), Gameday Men's Health now provides access to FDA-approved [KYZATREX](#), a prescription medication for adult men who have low or no testosterone due to certain medical conditions, in all Gameday Men's Health centers across 48 states. KYZATREX is available in an oral form, providing a non-invasive and convenient alternative to traditional injection-based methods.

Gameday Men's Health is a pioneering health clinic designed to help men reclaim their lives by optimizing four common areas of male concern - low testosterone, erectile dysfunction and enhancement, weight loss, and vitamin therapy. With in-house labs, expert medical teams, and personalized treatment plans, Gameday delivers discreet, effective solutions to support men's optimal health and vitality.

Shalin Shah, CEO of Marius Pharmaceuticals, says, "Given the staggering numbers of testosterone deficient men across the country, we are glad to see KYZATREX offered at one of the most rapidly growing men's clinics. It is critical that we normalize this critical, metabolic therapy so men feel comfortable getting the care that they need and glad to see Gameday solving this issue."

The launch of KYZATREX at Gameday Men's Health comes at a time when testosterone deficiency is a rising global epidemic as it affects approximately four in 10 men older than 45 years and 30-50% of men with obesity or type 2 diabetes, according

to the [Endocrine Society](#) (2022). Testosterone deficiency is bi-directional with metabolic diseases and early research indicates a role in further conditions such as depression and inflammatory diseases.

While TRT has traditionally consisted of injections, implanted pellets, patches, or gels, KYZATREX instead delivers testosterone through a twice-daily, softgel capsule that is safe and convenient. The oral delivery excludes the administration pain, mess, transference risk to others around you, and changes to eating habits which can occur with other TRT delivery systems. KYZATREX is primarily absorbed via the lymphatic system, effectively bypassing the liver and avoiding toxicity.

“Our goal has always been to make men's health accessible and adaptable. Oral TRT provides men with a choice in TRT that aligns with their preferences, allowing them to feel their best with minimal interruption to their daily lives, ” said Evan Miller, CEO and Founder of Gameday Men’s Health.

For more information about Gameday Men’s Health visit gamedaymenshealth.com. For more information about KYZATREX, visit www.kyzatrex.com, and for more information about Marius Pharmaceuticals, visit www.mariuspharma.com.

About Marius Pharmaceuticals

Marius Pharmaceuticals strives to better the lives of patients by focusing on therapies designed for hypogonadism or Testosterone Deficiency. The company's vision is to holistically improve metabolic health and mitigate significant unnecessary costs to the global healthcare system. For more information, please visit www.mariuspharma.com.

About Gameday Men’s Health

Gameday Men's Health is a premier men’s health clinic offering a range of services, including testosterone replacement therapy, erectile dysfunction treatment, weight loss programs, and vitamin therapy. Founded in 2018, this franchise is designed to help men transform their lives with a simple, three-step signature process: testing, proprietary wellness plans, and personalized treatment sessions. For more information, please visit www.gamedaymenshealth.com

About KYZATREX® (testosterone undecanoate)

KYZATREX is a proprietary softgel oral formulation absorbed primarily via the lymphatic system (meaning it is not toxic to the liver) and indicated in adult males for conditions associated with a deficiency or absence of endogenous testosterone. The safety and efficacy of KYZATREX was demonstrated in a phase 3, multi-center, open-label, six-month study in 155 hypogonadal males between 18 and 65 years of age with documented hypogonadism, as defined by a below normal serum testosterone level (≤ 281 ng/dL) and at least one sign or symptom of testosterone deficiency. In the efficacy population (n=139), 88 percent of hypogonadal men treated with KYZATREX achieved a mean plasma total testosterone concentration (Cavg) over 24 hours within the normal range (222-800 ng/dL) on the final pharmacokinetic (PK) visit of the study at

Day 90 (primary endpoint). Based on exploratory endpoints, patients who received KYZATREX reported improvements in symptoms of low testosterone, including quality of life, energy/fatigue, erectile function, sexual intercourse, and mood. The most common side effect reported in ≥ 2 percent of KYZATREX patients was increased blood pressure (2.6%). The safety and efficacy of KYZATREX in males less than 18 years old have not been established.

Please see additional Important Safety Information for KYZATREX below, including Boxed Warning for potential increased blood pressure, or visit www.kyzatrex.com.

Important Safety Information for KYZATREX® (Testosterone Undecanoate Capsules)

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 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.