



© TESTOSTERONE UNDECANOATE CAPSULES

KYZATREX “Practice in a Box”

Description Copy | How to Talk About KYZATREX

Use: Partnering providers can utilize this patient-friendly KYZATREX description in their website copy or in other marketing materials as appropriate.

Short Description

KYZATREX® (testosterone undecanoate) CIII Capsules 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 an FDA-approved oral form of testosterone replacement therapy that’s easy to take and up to 96% effective in helping patients achieve healthy testosterone levels.^{1,2*}

*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 Site 104). Based on patients who completed the study (n=127), 96% of patients achieved normal testosterone levels at Day 90.

References:

1. KYZATREX [prescribing information]. Raleigh, NC: Marius Pharmaceuticals; 2022.
2. 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. 2024;doi:10.1177/17562872241241864

Long Description

KYZATREX® (testosterone undecanoate) CIII Capsules 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 an FDA-approved oral form of testosterone replacement therapy that’s easy to take and up to 96% effective in helping patients achieve healthy testosterone levels.^{1,2*}

*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 Site 104). Based on patients who completed the study (n=127), 96% of patients achieved normal testosterone levels at Day 90.

KYZATREX is not a gel, injection, pellet, or patch. Just two KYZATREX capsules taken twice daily with food help restore testosterone to normal levels and keep it there.

No changes in diet or eating habits are required to accommodate KYZATREX, helping it fit seamlessly into your daily routine with adjustable dosing options to find the right balance for you.

How to Use this Description Copy

Include the following indication statement and additional information wherever this description is utilized:

KYZATREX® (testosterone undecanoate) CIII capsules is an oral testosterone treatment for adult men who have low or no testosterone levels due to certain medical conditions.

Please see Important Safety Information, including Boxed Warning, below and accompanying Full [Prescribing Information](#).

Important Safety Information for KYZATREX

*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 Site 104). Based on patients who completed the study (n=127), 96% of patients achieved normal testosterone levels at Day 90.

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.

1. 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.
2. If your blood pressure cannot be controlled, KYZATREX may need to be stopped.
3. 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.

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.

KYZATREX may cause other serious side effects including:

1. **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.
2. **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.
3. **Increased risk of prostate cancer.**
4. **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.
5. **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.
6. **In large doses, KYZATREX may lower your sperm count.**
7. **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).
8. **Swelling of your ankles, feet, or body (edema), with or without heart failure.**
9. **Enlarged or painful breasts.**
10. **Breathing problems while you sleep (sleep apnea).**