

KYZATREX® (testosterone undecanoate) CIII Capsules

Pharmacy Information

KYZATREX is a prescription 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 on the next page.



© TESTOSTERONE UNDECANOATE CAPSULES



Care Delivery

Providers can submit eRx on EMR for Fulfillment through HealthWarehouse:

Rx Info

NPI: **1619252160**

NCPDP: **1832674**

Coverage area

Health Warehouse Ships Nationwide

Location

HealthWarehouse.com

7107 Industrial Road

Florence, KY 41042

PHONE: **(800) 748-7001**

FAX: **(888) 870-2808**



Care Delivery

Providers can submit eRx on EMR for Fulfillment through EPIQ Scripts Pharmacy:

Rx Info

NPI: **1790415883**

NCPDP: **5936919**

Coverage area

EPIQ Scripts Pharmacy ships to all states except AL

Location

EPIQ Scripts LLC

465 W. President George Bush Hwy, Suite

#240 Richardson, TX 75080

PHONE: **(833) 654-3553**

FAX: **(888) 522-6059**

IMPORTANT SAFETY INFORMATION FOR KYZATREX® (testosterone undecanoate)

WARNING: BLOOD PRESSURE INCREASES

- KYZATREX® can cause blood pressure (BP) increases that can increase the risk of major adverse cardiovascular events (MACE), including non-fatal myocardial infarction, non-fatal stroke and cardiovascular death.
- Before initiating KYZATREX®, consider the patient's baseline cardiovascular risk and ensure BP is adequately controlled.
- Periodically monitor for and treat new-onset hypertension or exacerbations of pre-existing hypertension and re-evaluate whether the benefits of KYZATREX® outweigh its risks in patients who develop cardiovascular risk factors or cardiovascular disease on treatment.
- Due to this risk, use KYZATREX® only for the treatment of men with hypogonadal conditions associated with structural or genetic etiologies.

Please see Important Safety Information and accompanying [Full Prescribing Information](#) on the next page.

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

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Rev. 06/2025



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Rev. 6/2025