

MEDICATION GUIDE

KYZATREX® (ky-ZAH-treks)

(testosterone undecanoate) capsules, for oral use, CIII

What is the most important information I should know about KYZATREX?

KYZATREX can cause serious side effects, including:

- **Increase in blood pressure.**
 - KYZATREX can increase your blood pressure, which can increase your risk of having a heart attack or stroke and can increase your 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 taking blood pressure medicines, new blood pressure medicines may need to be added or your current blood pressure medicines may need to be changed 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.

What is KYZATREX?

- KYZATREX is a prescription medicine that contains testosterone. KYZATREX is used to treat adult men who have low or no testosterone due to certain medical conditions.
- It is not known if KYZATREX is safe or effective in children younger than 18 years old. Improper use of KYZATREX may affect bone growth in children.
- KYZATREX is a controlled substance (CIII) because it contains testosterone that can be a target for people who abuse prescription medicines. Keep your KYZATREX in a safe place to protect it. Never give your KYZATREX to anyone else, even if they have the same symptoms you have. Selling or giving away this medicine may harm others and is against the law.
- KYZATREX is not meant for use by women.

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 ingredients in KYZATREX. See the end of this Medication Guide for a complete list of ingredients in KYZATREX.
- have low testosterone without certain medical conditions. For example, 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.
- 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
- medicines that increase blood pressure such as some cold medicine and pain medicines

Know the medicines you take. Ask your healthcare provider or pharmacist for a list of these medicines, if you are not sure. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I take KYZATREX?

- Take KYZATREX exactly as your healthcare provider tells you take it.
- Take KYZATREX by mouth 2 times daily. Take 1 time in the morning and take 1 time in the evening. If your dose is 100 mg daily, take 1 time in the morning.
- Take KYZATREX with food.
- Your healthcare provider may change your KYZATREX dose. Do not change your KYZATREX dose without talking to your healthcare provider.

What are the possible side effects of KYZATREX?

KYZATREX may cause serious side effects including:

- See **“What is the most important information I should know about KYZATREX?”**
- **Increase in red blood cell count (hematocrit) or hemoglobin.**
 - KYZATREX increases red blood cell counts in some patients. High red blood cell counts increase the risk of blood clots, strokes, and heart attacks.
 - You may need to stop KYZATREX if your red blood cell count increases.
 - Your healthcare provider should check your red blood cell count and hemoglobin while you take KYZATREX.
- **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.** Your healthcare provider should check you for prostate cancer or any other prostate problems before you start and while you take KYZATREX.
- **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. Your healthcare provider should check you for signs of abuse before and during treatment with KYZATREX.
- **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.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

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

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store KYZATREX?

- Store KYZATREX at room temperature between 68°F to 77°F (20°C to 25°C).
- Store KYZATREX in a dry place.

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

How should I throw away (dispose of) KYZATREX?

- Throw away unused KYZATREX via a take-back option.
- If a take-back option is unavailable, follow FDA instructions at www.fda.gov/drugdisposal for properly throwing away medicine.

General information about the safe and effective use of KYZATREX

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use KYZATREX for a condition for which it was not prescribed. Do not give KYZATREX to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about KYZATREX that is written for health professionals.

What are the ingredients in KYZATREX?

Active ingredient: testosterone undecanoate

Inactive ingredients: DL-alpha-tocopheryl acetate (Vitamin E), phytosterol esters, polyoxyl 40 hydrogenated castor oil and propylene glycol monolaurate. The ingredients of the gelatin capsule shells are gelatin, glycerin, purified water, sorbitol, and titanium dioxide.

Marketed by:

Marius Pharmaceuticals
Raleigh, NC 27615

For more information, go to www.KYZATREX.com or call 1-833-949-5040

This Medication Guide has been approved by the U.S. Food and Drug Administration

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