FOR HCPs

KYZATREX® Titration Guide

Check serum testosterone concentration at least 7 days after starting treatment or after dosage adjustment, 3 to 5 hours after the morning dose. Periodically monitor serum testosterone concentration.

RECOMMENDED STARTING DOSE

- Two 100mg soft gels twice daily (400mg total per day)

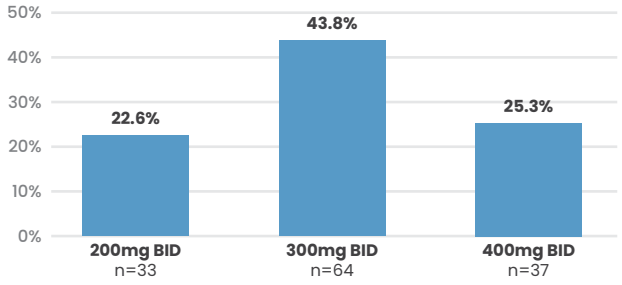
PRIMARY DOSES

- All primary doses are 4 soft gels per day - 2 in AM and 2 in PM
- 400mg daily dose: KYZATREX 100mg ii po bid #120
- 600mg daily dose: KYZATREX 150mg ii po bid #120
- 800mg maximum daily dose: KYZATREX 200mg ii po bid #120

KYZATREX®
TESTOSTERONE UNDECANOATE CAPSULES

PRIMARY DOSE DISTRIBUTION[1]

MRS-TU-2019EXT STUDY



Doses with >20% of patients at Day 90

KYZATREX® (testosterone undecanoate) capsules, CIII, is indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone.

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 additional Important Safety Information on back and accompanying Full Prescribing Information.

IMPORTANT SAFETY INFORMATION

INDICATION

KYZATREX® (testosterone undecanoate) capsules, CIII, is indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:

- Primary hypogonadism (congenital or acquired): testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone (FSH), luteinizing hormone (LH)) above the normal range.
- Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low serum testosterone concentrations but have gonadotropins in the normal or low range.

Limitations of Use

Safety and efficacy of KYZATREX in males less than 18 years old have not been established.

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- **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.**
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Contraindications

KYZATREX is contraindicated in patients with carcinoma of the breast or known or suspected carcinoma of the prostate; women who are pregnant (testosterone may cause fetal harm); patients with known hypersensitivity to KYZATREX or any of its ingredients; and men with hypogonadal conditions that are not associated with structural or genetic etiologies, as KYZATREX has not been established for these conditions and there is a risk of increased BP that can increase the risk of MACE.

Warnings and Precautions

Polycythemia. Check hematocrit prior to initiation and every 3 months during treatment to detect increased red blood cell mass and polycythemia. If hematocrit becomes elevated, stop KYZATREX until the hematocrit decreases to an acceptable level. If hematocrit increases after KYZATREX is restarted, discontinue treatment.

Cardiovascular Risk. Long-term clinical trials have not been conducted to assess the cardiovascular outcomes of testosterone replacement therapy in men. Other studies have been inconclusive for determining the risk of MACE with testosterone use compared to non-use.

Worsening of Benign Prostatic Hyperplasia (BPH) and Potential Risk of Prostate Cancer. Monitor patients for worsening of signs and symptoms of BPH. Evaluate patients for prostate cancer prior to initiating and during treatment with androgens.

Venous Thromboembolism (VTE). VTE, including deep vein thrombosis (DVT) and pulmonary embolism (PE), have been reported in patients using testosterone. Discontinue KYZATREX if VTE is suspected and initiate appropriate workup and management.

Abuse of Testosterone and Monitoring of Testosterone Concentrations. Testosterone has been subject to abuse, typically at doses higher than indicated and in combination with other anabolic androgenic steroids. If abuse is suspected, check testosterone levels to ensure they are within therapeutic range. Counsel patients concerning the serious adverse reactions associated with abuse and consider the possibility of abuse in suspected patients who present with serious cardiovascular or psychiatric adverse events.

Potential for Adverse Effects on Spermatogenesis. Large doses of androgens can suppress spermatogenesis. Inform patients of this risk before prescribing KYZATREX.

Edema. Edema may occur in patients with pre-existing cardiac, renal, or hepatic disease. In addition to discontinuing KYZATREX, diuretic therapy may be required.

Sleep Apnea: KYZATREX may potentiate sleep apnea in some patients, especially those with risk factors such as obesity or chronic lung disease.

Lipid Changes. KYZATREX may affect serum lipid profiles. Monitor patient lipid concentrations periodically: if necessary, adjust dosage of lipid lowering drug(s) or discontinue KYZATREX.

Other warnings include: hepatic adverse effects from prolonged use of high doses of methyltestosterone; gynecomastia; hypercalcemia in cancer patients; and decreased thyroxine-binding globulin.

Adverse Events

The most common adverse reaction of KYZATREX (incidence ≥ 2%) is hypertension (2.6%).

Drug Interactions

Insulin. KYZATREX can cause changes in insulin sensitivity or glycemic control. Androgens may decrease blood glucose requiring a decrease in the dose of anti-diabetic medication.

Oral Vitamin K Antagonist Anticoagulants. Anticoagulant activity may be seen with androgens. More frequent monitoring of international normalized ratio (INR) and prothrombin time are recommended in patients taking warfarin, especially at initiation and termination of androgen therapy.

Corticosteroids. Concurrent use of testosterone with corticosteroids may increase fluid retention and requires careful monitoring, particularly in patients with cardiac, renal, or hepatic disease.

Medications that May Also Increase Blood Pressure. Concomitant administration of medications drugs known to Increase BP with KYZATREX may lead to additional BP increases.

Use in Specific Populations

Females. KYZATREX is contraindicated in pregnant women and is not indicated for use in females.

Pediatric Use. The safety and efficacy of KYZATREX in pediatric patients less than 18 years old have not been established. Use in pediatric patients may result in acceleration of bone age and premature closure of epiphyses.

Geriatric Use. KYZATREX clinical studies did not include patients ≥65 years. It is unknown whether these patients respond differently from younger adult patients or have an increased risk of cardiovascular disease and prostate cancer. Geriatric patients treated with androgens may be at risk for worsening of signs and symptoms of BPH.

Please note that this information is not comprehensive. Please click here for the Full Prescribing Information, including BOXED WARNING.

To report SUSPECTED ADVERSE REACTIONS, contact Marius Pharmaceuticals at 1-833-949-5040 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

References

1. Data on file. Raleigh, NC: Marius Pharmaceuticals, 2020.

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KYZATREX®