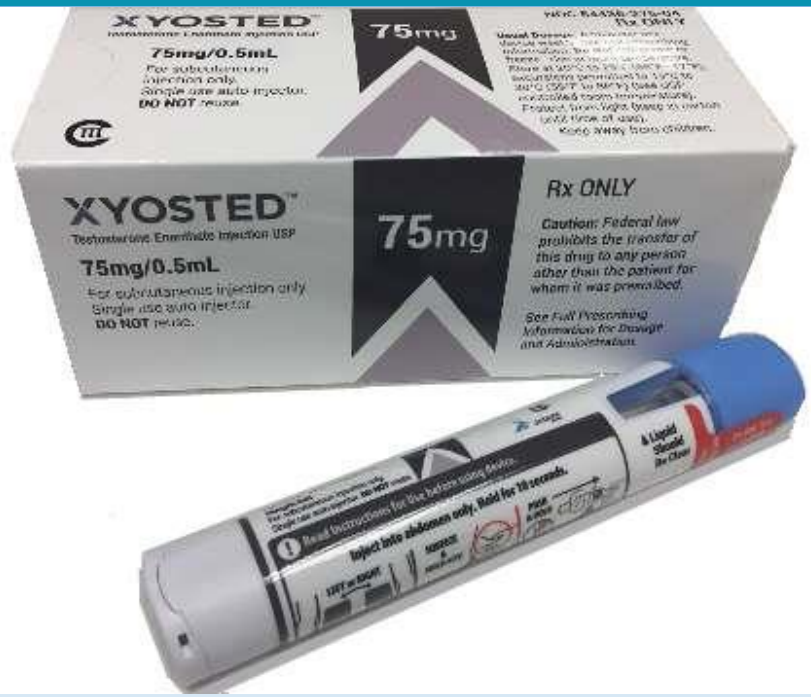
Xyosted (testosterone enanthate)



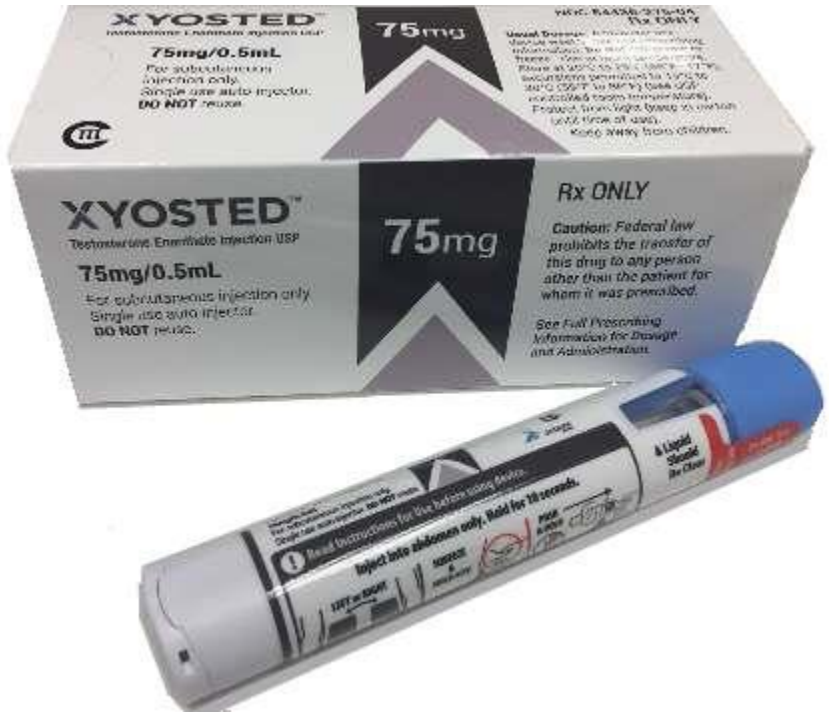
NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Xyosted
- **Generic name:** Testosterone enanthate
- **Pharmacological class:** Androgen
- **Strength and Formulation:** 50mg, 75mg, 100mg; per 0.5mL; soln for SC inj; in sesame oil; preservative-free
- **Manufacturer:** Antares Pharma
- **How supplied:** Single-dose autoinjectors—4
- **Legal Classification:** CIII

Xyosted


XYOSTED
75mg/0.5mL
For subcutaneous injection only.
Single use auto injector.
DO NOT reuse
75mg
XYOSTED
Testosterone Enanthate Injection USP
75mg/0.5mL
For subcutaneous injection only
Single use auto injector
DO NOT reuse.
75mg
Rx ONLY
Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.
See Full Prescribing Information for Dosage and Administration.

Indication

- Testosterone replacement therapy in adult males with congenital or acquired primary hypogonadism or hypogonadotropic hypogonadism

- **Limitations of use:** Not established in men with age-related hypogonadism or men aged <18yrs

Dosage & Administration

- Prior to treatment, confirm diagnosis by ensuring serum testosterone is below normal range as measured in the AM on at least 2 separate days
- Give as SC inj into abdomen
- **≥18yrs:** 75mg once weekly
- Decrease by 25mg if total testosterone trough level ≥650ng/dL; or, increase by 25mg if <350ng/dL

Considerations for Special Populations

- **Pregnancy:** See Contraindications
- **Nursing mothers:** Not indicated for use in females
- **Pediatric:** <18yrs: not established
- **Elderly:** May be at risk for worsening signs and symptoms of BPH

Contraindications

- Male breast or prostate cancer
- Pregnancy
- Hypogonadal conditions not associated with structural or genetic etiologies

Boxed Warning

- Blood pressure increases

Warnings/Precautions

- BP increases can occur and can increase the risk for major adverse cardiovascular (CV) events (eg, MI, stroke, death)
- Consider baseline cardiovascular risk and ensure BP is controlled prior to initiation
- Monitor BP approx. 6 weeks after initiating and periodically thereafter for new onset hypertension or exacerbations; re-evaluate benefits/risks if CV risk factors or disease develops

Warnings/Precautions

- Measure **total testosterone** trough levels after 6 weeks of dosing, then 6 weeks after dose adjustment, and periodically during treatment
- Monitor **hematocrit** prior to initiation and every 3 months during therapy; if elevation occurs, withhold until acceptable level; permanently discontinue if elevated after restarting treatment
- Increased risk of worsening of BPH; monitor

Warnings/Precautions

- Evaluate for **prostate cancer** prior to and during therapy
- Monitor for venous thromboembolism; discontinue if suspected
- Testosterone and/or other anabolic androgenic steroid abuse
- **Discontinue** and evaluate if signs/symptoms of hepatic dysfunction (eg, jaundice) occur

Warnings/Precautions

- Pre-existing cardiac, renal, or hepatic disease (discontinue if edema occurs)
- Possible **sleep apnea** in patients with obesity or chronic lung diseases
- Monitor **lipid** profile (esp. after starting therapy), serum calcium (in cancer patients at risk of hypercalcemia/hypercalciuria) periodically

Warnings/Precautions

- Risk of depression or suicide
- May suppress spermatogenesis
- Elderly
- Not for use in women

Interactions

- Additive effects with concomitant medications that increase BP
- May alter **insulin** sensitivity or glycemic control; reduce dose of antidiabetic agents if needed
- Monitor **INR** and **PT** with concomitant oral anticoagulants
- Increased fluid retention with corticosteroids
- May affect **thyroid** levels

Adverse Reactions

- Hematocrit increase
- Hypertension
- PSA increase
- Injection site bruising
- Headache
- Worsening BPH
- Prostate cancer
- Venous thromboembolism
- Edema
- Hepatic dysfunction
- Gynecomastia

Mechanism of Action

- Endogenous androgens are responsible for the normal growth and development of the male sex organs and for maintenance of secondary sex characteristics
- Male hypogonadism, a clinical syndrome resulting from insufficient secretion of testosterone, has 2 main etiologies
- Primary hypogonadism is caused by defects of the gonads, such as Klinefelter’s syndrome or Leydig cell aplasia, whereas secondary hypogonadism is the failure of the hypothalamus (or pituitary) to produce sufficient gonadotropins (FSH, LH)

Clinical Studies

- Xyosted was evaluated in a 52-week, open-label study (N=150) in adult males with hypogonadism
- The study included a screening phase, a treatment titration phase, and an extended treatment phase

Clinical Studies

- Patients self-administered an initial dose of 75mg once weekly
  - The dose was increased by 25mg at Week 7 if the Week 6 serum total testosterone concentration at the end of the dosing interval (C_{trough}) was <350ng/dL
  - The dose was decreased by 25mg if the C_{trough} was ≥650ng/dL

Clinical Studies

- The **primary endpoint** was the percentage of patients with a time-averaged serum total testosterone concentration (C_{avg}) over the 7-day dosing interval (0 to 168 hours) within the normal range (300 to 1100ng/dL) at Week 12

Clinical Studies

- **Secondary endpoints** were the percentage of patients with a maximum total testosterone concentration (C_{max}) above predetermined limits:
  - >1500ng/dL
  - 1800 to 2500ng/dL
  - >2500ng/dL

Clinical Studies

- Data showed **90%** of patients (N=135) who received Xyosted had a serum total testosterone concentration $C_{avg(0\text{-}168h)}$ within the normal range at Week 12
- No patients had C_{max} >1500ng/dL at Week 12

- For more clinical study data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

https://www.empr.com/xyosted/drug/34901/