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Take CME Exams

Revised 3/4/25: On February 28, the FDA recommended revisions to the labels of testosterone products removing language about an increased risk of adverse cardiovascular outcome and adding information about possible increases in blood pressure. The online version of the article has been revised to reflect these changes.

IN BRIEF

Azmiro – A Single-Dose Injectable Formulation of Testosterone Cypionate

The FDA has approved *Azmiro* (Azurity), the first injectable formulation of testosterone cypionate to become available in single-dose vials and prefilled syringes for treatment of males with conditions associated with a deficiency or absence of endogenous testosterone. Injectable testosterone cypionate has been available in multidose vials (*Depo-Testosterone*, and generics) for many years. Testosterone enanthate (*Xyosted*) is available in prefilled autoinjectors for use in adult men.¹ No testosterone products are approved for treatment of low testosterone levels due solely to aging. All testosterone products are classified as schedule III controlled substances.

Pronunciation Key

Azmiro: az meer oh

THE NEW PRODUCT – Testosterone cypionate can crystallize in solution when it is stored at lower-than-recommended temperatures (less than 20-25°C; 68-77°F). According to its manufacturer, *Azmiro* is more stable than testosterone cypionate in multidose formulations and should not crystallize.²

CLINICAL STUDIES – FDA approval of *Azmiro* was based on the results of an open-label, single-dose, two-way crossover pharmacokinetic study (summarized in an FDA review document) in 28 hypogonadal men. The new single-dose prefilled testosterone cypionate formulation was bioequivalent to the multidose formulation of injectable testosterone cypionate (*Depo-Testosterone*).²

ADVERSE EFFECTS – The most common adverse effects of *Azmiro* in the single-dose study were mild injection-site reactions; the incidence was similar to that with *Depo-Testosterone*.

All testosterone products can cause erythrocytosis. Hematocrit levels should be assessed before starting treatment and periodically thereafter; testosterone therapy should be withheld for a first elevation until the hematocrit returns to an acceptable level and permanently discontinued for a second elevation.

Testosterone replacement therapy can cause venous thromboembolism, azoospermia, edema, gynecomastia, hypercalcemia, hepatic adverse effects, increases in blood pressure, and decreases in both HDL-cholesterol and thyroxine-binding globulin (TBG) levels. It has been associated

Table 1. Some Injectable Testosterone Replacement Products¹

Drug	Some Formulations	Usual Adult Dosage ²	Cost ³
Testosterone cypionate – generic <i>Depo-Testosterone</i> (Pfizer) <i>Azmiro</i> (Azurity)	1, 10 mL vials (100, 200 mg/mL) ^{4,5} 1 mL single-dose vials, prefilled syringes (200 mg/mL) ⁵	50-400 mg IM q2-4 weeks	\$65.70 138.20 250.00
Testosterone enanthate – generic <i>Xyosted</i> (Antares Pharma)	5 mL vials (200 mg/mL) ⁵ 0.5 mL auto-injectors (50, 75, 100 mg/0.5 mL)	100-200 mg IM q2 weeks 50-100 mg SC once/week	73.00 643.10
Testosterone undecanoate – <i>Aveed</i> (Endo) ⁷	3 mL vials (250 mg/mL)	750 mg IM at 0 and 4 weeks, then q10 weeks	1976.60

1. All testosterone products are classified as schedule III controlled substances.

2. Dosage and titration is based on total serum testosterone concentrations.

3. Approximate WAC for one 10-mL vial (200 mg/mL) of testosterone cypionate, one *Azmiro* prefilled syringe, one 5-mL vial of testosterone enanthate, four *Xyosted* auto-injectors, or one 3-mL vial of *Aveed*. WAC = wholesaler acquisition cost or manufacturer's published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: AnalySource® Monthly. February 5, 2025. Reprinted with permission by First Databank, Inc. All rights reserved. ©2025. www.fdbhealth.com/policies/drug-pricing-policy.

4. The 100-mg/mL formulation is only available in a 10-mL vial.

5. Vial should be discarded within 28 days after being opened or accessed (USP General Chapter 797).

6. The prefilled syringes should only be used to administer a 200-mg dose; the single-dose vials should be used to deliver all other doses.

7. Only available to certified prescribers through a REMS program because of the risk of serious pulmonary oil microembolism reactions and anaphylaxis.

with new-onset and worsening of sleep apnea, worsening of benign prostatic hyperplasia (BPH), and increases in prostate-specific antigen (PSA) levels; whether it increases the risk of prostate cancer is unclear.³ Like other testosterone products, *Azmiro* is contraindicated for use in patients with breast or prostate cancer.

DOSAGE AND ADMINISTRATION – Single-dose vials and prefilled syringes of *Azmiro* contain 200 mg of testosterone cypionate in 1 mL of solution. The recommended dosage is 50-400 mg administered by a healthcare provider every 2-4 weeks as a deep injection into the gluteal muscle. The prefilled syringes should only be used to administer a 200-mg dose; the single-dose vials can be used for all other doses.

CONCLUSION – *Azmiro*, a single-dose vial and prefilled syringe formulation of testosterone cypionate, is claimed to be more stable than testosterone cypionate multidose formulations (*Depo-Testosterone*, and generics) and should not crystallize. It is administered as a deep intragluteal injection by a healthcare provider every 2 to 4 weeks. ■

1. *Xyosted* – a testosterone auto-injector for hypogonadism. *Med Lett Drugs Ther* 2019; 61:37.
2. FDA, CDER. Multi-discipline review. Testosterone cypionate injection. June 2, 2022. Available at: <https://bit.ly/3CCH6eO>. Accessed February 27, 2025.
3. Safety of testosterone replacement therapy. *Med Lett Drugs Ther* 2016; 58:33.

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