

Supplemental Approvals

Generic Name (Trade Name—Company)

October 2, 2018

Testosterone enanthate

(Xyosted—Antares Pharma)

FDA approves first S.C. testosterone enanthate injection for once-weekly, at-home self-administration

Uses/Notes

[Antares Pharma announced](#) FDA approval of testosterone enanthate, the first testosterone replacement therapy for conditions associated with a deficiency or absence of endogenous testosterone in adult males.

The product is self-administered subcutaneously once weekly at home with an easy-to-use, single-dose, disposable QuickShot auto injector. It comes in three dosage strengths: 50 mg, 75 mg, and 100 mg.

In Phase III clinical trials, the product was shown to produce physiologically normal levels of testosterone with a narrow peak-to-trough ratio. According to the principal investigator, the S.C. dosing removes transfer concerns commonly associated with gels and potentially reduces the need for in-office injection procedures that may require more frequent patient visits.

The product can cause blood pressure elevations that can increase the risk for major adverse cardiovascular events (MACE), including nonfatal myocardial infarction, nonfatal stroke and cardiovascular death, with greater risk for MACE in patients with cardiovascular risk factors or established cardiovascular disease.

The most commonly reported adverse reactions in clinical trials were hematocrit increases, hypertension, prostate-specific antigen increases, injection-site bruising, and headache.

Recommended dosage is 100–400 mg every 4 weeks.

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