IMPORTANT SAFETY INFORMATION

DEPO-Testosterone CIII (testosterone cypionate injection, USP) is contraindicated in patients with known hypersensitivity to the drug, males with carcinoma of the breast, males with known or suspected carcinoma of the prostate gland, women who are or who may become pregnant and patients with serious cardiac, hepatic or renal disease.

Hypercalcemia may occur in immobilized patients. If this occurs, the drug should be discontinued.

Prolonged use of high doses of androgens has been associated with development of hepatic adenomas, hepatocellular carcinoma, and peliosis hepatis - all potentially life-threatening complications.

Geriatric patients treated with androgens may be at an increased risk of developing prostatic hypertrophy and prostatic carcinoma although conclusive evidence to support this concept is lacking.

Edema with or without congestive heart failure, may be a serious complication in patients with pre-existing cardiac, renal or hepatic disease.

Gynecomastia may develop and occasionally persists in patients being treated for hypogonadism.

This product contains benzyl alcohol. Benzyl alcohol has been reported to be associated with a fatal "Gasping Syndrome" in premature infants.

Androgen therapy should be used cautiously in healthy males with delayed puberty. The effect on bone maturation should be monitored by assessing bone age of the wrist and hand every 6 months. In children, androgen treatment may accelerate bone maturation without producing compensatory gain in linear growth. This adverse effect may result in compromised adult stature. The younger the child the greater the risk of compromising final mature height.

This drug has not been shown to be safe and effective for the enhancement of athletic performance. Because of the potential risk of serious adverse health effects, this drug should not be used for such purpose.

Patients with benign prostatic hypertrophy may develop acute urethral obstruction. Priapism or excessive sexual stimulation may develop. Oligospermia may occur after prolonged administration or excessive dosage. If any of these effects appear, the androgen should be stopped and if restarted, a lower dosage should be utilized.

Testosterone cypionate should not be used interchangeably with testosterone propionate because of the differences in duration of action.

Testosterone cypionate *is not* for intravenous use.
DEPO-Testosterone is Pregnancy Category X.

DEPO-Testosterone is not recommended for use in nursing mothers.

Safety and effectiveness in pediatric patients below the age of 12 years have not been established.

Other side effects that have occurred with some androgens include hirsutism, male pattern baldness, seborrhea, acne, retention of sodium, chloride, water, potassium, calcium and inorganic phosphates, nausea, cholestatic jaundice, alterations in liver function tests, suppression of clotting factors II, V, VII and X, bleeding in patients on concomitant anticoagulation therapy and polycythemia. Increased or decreased libido, headache, anxiety, depression and generalized parasthesia. Hypersensitivity, including skin manifestations and anaphylactoid reactions.

References: 1. US Food and Drug Administration. Label and approval history. http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails. Accessed June 24, 2013. **2.** Depo®-Testosterone [package insert]. New York, NY: Pfizer Inc; 2006.