The Androderm system has six components as shown in Figure 1. Proceeding from the top toward the surface attached to the skin, the system is composed of (1) a metalized polymer/Surlyn® (ethylene-methacrylic acid copolymer)/ethylene vinyl acetate backing, (2) a permeable polyethylene microporous membrane and a larger non-permeable polyethylene microporous membrane, and a large peripheral layer of acrylic adhesive surrounding the central, drug-containing delivery reservoir (3). Together, the three layers constitute the adhesive layer of the transdermal system. Upon removal of the protective liner from the drug delivery reservoir, the reservoir is attached to and removed with the release liner, (4) a silicone-coated polyester film, which is removed before the system can be used. The releasing polymer layer (5) is a 123 45 . . . 116 117 119.

The Androderm system delivers physiologic concentrations of testosterone to the skin. The active ingredient in the system is testosterone. The transdermal system delivers testosterone to the skin in a manner that mimics the normal circadian rhythm of healthy young men. Average steady-state testosterone concentration profiles during application of 1, 2, or 3 2.5 mg systems to the abdomen, back, thighs, and upper arm resulted in average testosterone concentrations of 3 to 4 mg per day. The amount of SHBG in serum and the total testosterone concentrations were comparable to those in normal young men. The transdermal system delivery of testosterone was consistent and reliable; and alterations in body musculature and fat distribution were noted in the majority of these patients. In a steady-state study of 12 hypogonadal men, nightly testosterone concentrations were measured using single-dose applications of two Androderm 2.5 mg systems applied at night to different sites in 34 hypogonadal men, application of two Androderm 2.5 mg systems to the abdomen, back, thighs, and upper arm resulted in average testosterone concentrations of 4 to 5 mg per 24 hours. The serum testosterone concentration profiles during application were similar for all sites (Table 2). The mean serum testosterone concentrations were measured using single-dose applications of two Androderm 2.5 mg systems applied at night to different sites in 34 hypogonadal men. The average serum testosterone concentrations were measured using single-dose applications of two Androderm 2.5 mg systems to the abdomen, back, thighs, and upper arm resulted in average testosterone concentrations of 4 to 5 mg per 24 hours. The serum testosterone concentration profiles during application were similar for all sites (Table 2). The mean serum testosterone concentrations were measured using single-dose applications of two Androderm 2.5 mg systems applied at night to different sites in 34 hypogonadal men.
Gynecomastia frequently develops and occasionally occurs during 1 year of Androderm treatment. Mild skin irritation may be ameliorated by treatment of the affected skin with over-the-counter topical hydrocortisone or clobetasol propionate cream. Applying a small amount of 0.1% triamcinolone acetonide cream (Rx) does not significantly alter transdermal absorption of testosterone from the system. Ointment formulations should not be used for pretreatment as they may significantly reduce testosterone absorption. Androderm (testosterone transdermal system) therapy for non-virilized patients may be initiated with 1.25 mg/day and increased as needed. HOW SUPPLIED Androderm (testosterone transdermal system) 2.5 mg/day Each system contains 12.2 mg testosterone USP for delivery of 2.5 mg of testosterone per day (see DESCRIPTION). Cartons of 60 systems NDC 52544-469-60 Androderm (testosterone transdermal system) 5 mg/day Each system contains 24.3 mg testosterone USP for delivery of 5 mg of testosterone per day (see DESCRIPTION). Cartons of NDC 52544-470-00 Storage and Disposal Store at room temperature, 15° to 30°C (59° to 86°F). Apply skin immediately after removal from the protective pouch. Do not store outside the pouch provided. Damaged systems should not be used. The drug remains active if the pouch is punctured. Discard systems in household trash in a manner that prevents accidental application or ingestion by children or pets. REFERENCES 1. Peppas, eds. Mirkovic the circular pattern of testosterone and metabolite levels with an enhanced transdermal delivery system. In Gurney, Junjinger, testoste- 2. Schroder FH. Androgens and carcinoma of the prostate. In Neischlag E, Behre HM, eds. Testosterone 4,983,395, 5,152,997, and 5,164,190. THE CLINICAL PHARMACOLOGY OF TESTOSTERONE AND ITS METABOLITES IN HUMANS. Stuttgart: Wiss. Verl. 2.5 mg/day or two Androderm 2.5 mg systems applied nightly for 24 hours, providing a total dose of 5 mg/day. The adhensive side of the Androderm system should be replaced every 2 to 3 days. Androderm 5 mg 6.25 mg/day or two Androderm 5 mg systems applied nightly for 24 hours, providing a total dose of 12.5 mg/day. The adhensive side of the Androderm system should be replaced every 2 to 3 days. ADVERSE REACTIONS Adverse Effects Associated with Injection or Oral Treatment 12.5 mg/day or two Androderm 5 mg systems applied nightly for 24 hours, providing a total dose of 5 mg/day. The adhensive side of the Androderm system should be replaced every 2 to 3 days. Androderm 5 mg 1.25 mg/day or two Androderm 2.5 mg systems applied nightly for 24 hours, providing a total dose of 2.5 mg/day. The adhensive side of the Androderm system should be replaced every 2 to 3 days. Androderm 2.5 mg 6.25 mg/day or two Androderm 5 mg systems applied nightly for 24 hours, providing a total dose of 12.5 mg/day. The adhensive side of the Androderm system should be replaced every 2 to 3 days. Androderm 5 mg