RISK EVALUATION AND MITIGATION STRATEGY (REMS)

ANDA 204571
Testosterone Topical Gel, CIII
Class of Drug: Androgen
Actavis Laboratories UT, Inc.
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I. Goal

The goal of this REMS is to inform patients about the serious risks associated with the use of Testosterone Topical Gel.

II. REMS Elements

A. Medication Guide

A Medication Guide will be dispensed with each Testosterone Topical Gel prescription in accordance with 21 CFR 208.24.

The Medication Guide is part of the REMS and is appended.