

Initial REMS Approval: 09/2015

ANDA 076744 Testosterone Gel 1% CIII

Drug Class and Formulation: Testosterone Gel Products

PAR PHARMACEUTICAL, INC.

Chestnut Ridge, NY 10977

Risk Evaluation and Mitigation Strategy (REMS)

I. GOAL(S):

The goal of this REMS is to inform patients about the serious risks associated with the use of testosterone gel 1%.

II. REMS ELEMENTS:

A. Medication Guide

A Medication Guide will be dispensed with each testosterone gel 1% prescription in accordance with 21 CFR 208.24. Testosterone gel 1% container or package labels will include an instruction alerting the pharmacist to provide the Medication Guide to each person to who the product is dispensed.