

NDA 21-015 ANDROGEL® (testosterone gel) 1% CIII

Drug Class and Formulation: Testosterone Gel Products

**Solvay Pharmaceuticals Inc.
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Risk Evaluation and Mitigation Strategy (REMS)

I. GOAL:

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

II. REMS ELEMENTS:

A. Medication Guide

A Medication Guide will be dispensed with each AndroGel (testosterone gel) 1% prescription in accordance with 21 CFR 208.24. One Medication Guide will be available in each carton of AndroGel 1% to assure that a copy will be available for distribution to patients using the product. AndroGel 1% container or package labels will include an instruction alerting the pharmacist to provide the Medication Guide to each person to whom the product is dispensed.

Solvay will include a Medication Guide with each twin pack carton containing two AndroGel 1% pumps. Instructions exist on the carton not to separate the twin packs. One Medication Guide will be included in each carton of 30 AndroGel 1% sachets.

B. Timetable for Submission of Assessments

Solvay Pharmaceuticals Inc. will submit REMS assessments to the FDA 18 months, 3 years, and 7 years from the date of the approval of the REMS, per the table below.

	Month/Year of Submission
1st REMS Assessment (18 months from approval date)	March 2011
2nd REMS Assessment (3 years from approval date)	September 2012
3rd REMS Assessment (7 years from approval date)	September 2016

To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. Solvay Pharmaceuticals will submit each assessment so that it will be received by the FDA on or before the due date.