

NDA 21-454 TESTIM[®] 1% (testosterone gel)

Class of Product: Androgen

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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 TESTIM[®] 1% (testosterone gel).

II. REMS ELEMENTS

A. Medication Guide

A Medication Guide will be dispensed with each TESTIM[®] 1% (testosterone gel) prescription.

TESTIM[®] 1% is supplied in unit-dose tubes that are packaged in two configurations for distribution to the consumer: 30-unit carton and 7-unit (sample) carton. A printed Medication Guide will be packaged in each 30-unit and each 7-unit carton, thereby ensuring that all patients receive a Medication Guide as prescribed in 21 CFR 208.24. Additionally, the 30-unit and 7-unit cartons both include the following statements:

Main panel and lid: Dispense the enclosed Medication Guide to each patient.

Side panel: Usual dose: See enclosed Medication Guide.

Patient: Please read accompanying Medication Guide

B. Timetable for Submission of Assessments

Auxilium Pharmaceuticals will submit REMS assessments to 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.

Auxilium Pharmaceuticals will submit each assessment so that it will be received by the FDA on or before the due date.