

Initial REMS Approval: 11/2010

Most Recent Modification: 05/2015

NDA 22-504
AXIRON[®] (testosterone) topical solution for topical use CIII

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

Class of Product: Testosterone

Eli Lilly and Company
Lilly Corporate Center, Indianapolis, Indiana 46285
Telephone: 317-276-2000

I. GOAL(S)

To inform patients about the serious risks associated with the use of AXIRON[®] (testosterone) topical solution.

II. REMS Elements

A. Medication Guide

A Medication Guide will be dispensed with each prescription of AXIRON[®] (testosterone) topical solution in accordance with 21 CFR 208.24.

Please see the appended Medication Guide.

B. Timetable for Submission of Assessments

Eli Lilly and Company will submit REMS assessments to the FDA at a minimum, 18 months, 3 years, and 7 years from the date of the initial approval of the REMS. 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.

Eli Lilly and Company will submit each assessment so that it will be received by the FDA on or before the due date.