

**Initial REMS Approval: 09/2009**

**Most Recent Modification: 05/2015**

**NDA 21-015 ANDROGEL<sup>®</sup> (testosterone gel) 1% CIII**

**Drug Class and Formulation: Testosterone Drug Products**

**AbbVie Inc.  
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**RISK EVALUATION AND MITIGATION STRATEGY (REMS)**

**I. GOAL:**

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.

**B. Timetable for Submission of Assessments**

AbbVie Inc. will submit REMS assessments to FDA by 18 months, 3 years and 7 years from the date of initial approval (September 18, 2009) of the AndroGel (testosterone gel) 1% 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 the assessment. AbbVie Inc. will submit each assessment so that it will be received by FDA on or before the due date.