

**Initial REMS Approval: 04/2011**  
**Most Recent Modification 09/2012**

NDA 22-309 AndroGel® (testosterone gel) 1.62% CIII

Drug Class and Formulation: Testosterone Gel Products

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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) 1.62%.

### **II. REMS ELEMENTS:**

#### **A. Medication Guide**

A Medication Guide will be dispensed with each AndroGel (testosterone gel) 1.62% prescription in accordance with 21 CFR 208.24.

#### **B. Timetable for Submission of Assessments**

Abbott Laboratories will submit REMS Assessments to FDA at 18 months, 3 years, and 7 years from the initial date (April 29, 2011) of the approval. 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.

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