

## **LAMICTAL (lamotrigine) XR (Extended Release Tablets)**

**Drug Class:** Anticonvulsant

**Applicant Name:** SmithKline Beecham d/b/a GlaxoSmithKline

**Applicant Address:** One Franklin Plaza, 200 North 16th Street, Philadelphia, PA 19102.

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## **RISK EVALUATION AND MITIGATION STRATEGY (REMS)**

### **I. GOAL:**

The goal of the REMS is to inform patients of the serious risks associated with LAMICTAL, including the increased risk of suicidal thoughts and behavior.

### **II. REMS ELEMENTS**

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

A Medication Guide will be dispensed with each LAMICTAL prescription.

- LAMICTAL XR is packaged as a single unit of use and a Medication Guide will be attached to each package. Each Medication Guide is barcode scanned to ensure that the correct version is being used and that the component is available for attaching to each package.

The label of each container or package of LAMICTAL will include a prominent instruction to authorized dispensers to provide a Medication Guide to each patient to whom the drug is dispensed, and state how the Medication Guide is provided.

Please see the appended Medication Guide.

#### **B. Communication Plan**

Not applicable.

#### **C. Elements to Assure Safe Use**

Not applicable.

#### **D. Implementation System**

Not applicable.

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

GlaxoSmithKline will submit REMS assessments to FDA 18 months, 3 years and 7 years from the date of initial approval of the REMS (May 29, 2009) according to the schedule below:

1<sup>st</sup> FDAAA assessment: November 29, 2010 (18 months from approval)

2<sup>nd</sup> FDAAA assessment: May 29, 2012 (3 years from approval)

3<sup>rd</sup> FDAAA assessment: May 29, 2016 (7 years from approval)

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

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.