

Initial REMS Approval: 08/2009

Last modified/revised: 06/2016

NDA 20427

NDA 22006

SABRIL® (vigabatrin) Drug

Class: Anticonvulsant

Lundbeck LLC

Deerfield, Illinois 60015

SABRIL REMS PROGRAM RISK EVALUATION & MITIGATION STRATEGY (REMS)

I. GOAL

The goal of the SABRIL REMS Program is to mitigate the risk of vision loss associated with SABRIL by:

- Ensuring that healthcare providers are educated about the risk of vision loss, the need to counsel patients about the risk, and the need for periodic visual monitoring.
- Ensuring that SABRIL is only dispensed to patients with documentation that patients are informed about the risk of vision loss associated with SABRIL and the need for periodic visual monitoring.

II. SABRIL REMS PROGRAM ELEMENTS

A. Elements To Assure Safe Use

1) Healthcare providers who prescribe SABRIL must be specially certified.

- a) To become specially certified to prescribe SABRIL in the SABRIL REMS Program, healthcare providers must:
 - i) Review the Prescribing Information for SABRIL.
 - ii) Enroll in the SABRIL REMS Program by completing and submitting the [SABRIL](#)

REMS Program Prescriber Enrollment and Agreement Form to the SABRIL REMS Program.

Currently enrolled prescribers must recertify within 90 calendar days of the approval of the SABRIL REMS Program modification (June 2016) or prior to prescribing SABRIL.

b) As a condition of certification, prescribers must:

i) Enroll each patient in the SABRIL REMS Program by doing the following:

(1) Counsel the patient/caregiver about the risks associated with SABRIL, including visual loss, and the need for periodic visual monitoring and provide a copy of the *What You Need to Know About SABRIL Treatment: A Patient Guide*.

(2) Complete the *SABRIL REMS Program Patient/Parent/Legal Guardian-Physician Agreement Form* for each patient and provide a completed copy to the patient/caregiver. The completed form should be submitted to the SABRIL REMS Program and a copy stored in the patient's records.

ii) Ensure that periodic visual monitoring, as described in the Prescribing Information, is performed on an ongoing basis for each patient.

iii) Report any adverse event suggestive of vision loss to the SABRIL REMS Program with all available information.

c) Lundbeck must:

i) Ensure that healthcare providers who prescribe SABRIL are specially certified in accordance with the requirements described above.

ii) Ensure that healthcare providers can complete the certification process online, by fax or by mailing the forms to the SABRIL REMS Program.

iii) Ensure that healthcare providers are notified when they have been certified by the SABRIL REMS Program.

iv) Maintain a validated, secure database of healthcare providers who are certified to prescribe SABRIL in the SABRIL REMS Program.

v) Ensure that healthcare providers meet the SABRIL REMS Program certification requirements.

- vi) De-certify healthcare providers who do not maintain compliance with the SABRIL REMS Program requirements.
- vii) Ensure that certified prescribers are provided access to the database of certified pharmacies and enrolled patients.
- viii) Provide the *SABRIL REMS Program Prescriber Enrollment and Agreement Form* and the Prescribing Information to healthcare providers who (1) attempt to prescribe SABRIL and are not yet certified, or (2) inquire about how to become certified.
- ix) Send the *SABRIL REMS Program Letter for Prescribers* within 30 calendar days of the approval of the SABRIL REMS Program modification (June 2016). The *SABRIL REMS Program Letter for Prescribers* will address the risk of visual loss and need for periodic visual monitoring as well as the changes which have occurred to the SABRIL REMS Program.

(1) Email and USPS mailing will be used as the primary method to disseminate the *SABRIL REMS Program Letter for Prescribers*. If an email is marked as unopened, a second email will be sent within 30 calendar days of the date the first email was sent. If the second email is marked as unopened, the appropriate *SABRIL REMS Program Letter for Prescribers* will be mailed within 30 calendar days of the date the second email was sent.

If an email address is not available or if the email is undeliverable, the appropriate *SABRIL REMS Program Letter for Prescribers* will be mailed within 30 calendar days of the date of the bulk mailing.

(a) **SABRIL REMS Program Letter for Prescribers:** The intended audience for the *SABRIL REMS Program Letter for Prescribers* is neurologists and other healthcare providers known or likely to prescribe SABRIL. The following materials will be appended to the letter: *Prescribing Information*

- x) Disseminate SABRIL REMS Program information at Scientific Meetings: The SABRIL REMS Program materials will be prominently displayed and disseminated together with responses to medical information requests at all relevant scientific meetings where Lundbeck has a presence (e.g., exhibit booth) for 18 months following the SABRIL REMS Program modification approval (June 2016).

The following materials are part of the SABRIL REMS Program and are appended:

- *SABRIL REMS Program Prescriber Enrollment and Agreement Form*;
- *What You Need to Know About SABRIL Treatment: A Patient Guide*;
- *SABRIL REMS Program Patient/Parent/Legal Guardian-Physician Agreement Form*; and
- *SABRIL REMS Program Letter for Prescribers*

2) Pharmacies that dispense SABRIL must be specially certified.

a) To become specially certified to dispense SABRIL in the SABRIL REMS Program, pharmacies must:

i) Designate an authorized representative to complete enrollment by submitting the *SABRIL REMS Program Pharmacy Enrollment Form* on behalf of the pharmacy.

Currently enrolled pharmacies must recertify within 90 calendar days of the approval of the SABRIL REMS Program modification (June 2016).

ii) Ensure the authorized representative must oversee implementation and compliance with the SABRIL REMS Program requirements by the following:

- (1) Ensure that all relevant staff involved in the dispensing of SABRIL are trained on the SABRIL REMS Program requirements.
- (2) Establish and adhere to procedures to verify that prescribers are certified and patients are enrolled in the SABRIL REMS Program prior to dispensing SABRIL.
- (3) Comply with requests to be audited by Lundbeck, FDA, or a third party to ensure that all processes and procedures are in place and are being followed for the SABRIL REMS Program and appropriate documentation is maintained and available upon request.
- (4) In the case of an inpatient pharmacy, ensure that the pharmacy does not dispense more than a 15-day temporary supply of SABRIL to an enrolled patient upon discharge from the healthcare facility.

b) Lundbeck must:

i) Send a one-time *SABRIL REMS Program Letter for Pharmacists* within 30 calendar days of the approval of the SABRIL REMS Program modification (June 2016). The *SABRIL REMS Program Letter for Pharmacists* will address the risk of visual loss and changes to the SABRIL REMS Program. *SABRIL REMS Program Letters*

for Pharmacists will be distributed by email. See section [A\(1\)\(c\)\(ix\)](#) for distribution information.

- (1) **SABRIL REMS Program Letter for Pharmacists:** The intended audience for the *SABRIL REMS Program Letter for Pharmacists* will be pharmacists who have dispensed or are likely to dispense SABRIL. The following materials will be appended to the letter: [Prescribing Information](#)
- ii) Ensure that SABRIL is dispensed only by pharmacies that are specially certified in accordance with the requirements described above.
- iii) Ensure that pharmacy certification can be completed online, by fax, or by mailing the forms to the SABRIL REMS Program.
- iv) Ensure that pharmacies are notified when they have been certified by the SABRIL REMS Program.
- v) Ensure that certified pharmacies are provided access to the database of certified healthcare providers and enrolled patients.
- vi) Verify every 12 months that the authorized representative's name and contact information corresponds to that of the current designated authorized representative for the certified pharmacy. If different, the pharmacy will be required to re-certify with a new appointed authorized representative.

The following materials are part of the SABRIL REMS Program and are appended:

- *SABRIL REMS Program Pharmacy Enrollment Form*
- *SABRIL REMS Program Letter for Pharmacists*

3) SABRIL will be dispensed to patients with documentation of safe-use conditions.

- a) To become enrolled in the SABRIL REMS Program, each patient/caregiver must sign a *SABRIL REMS Program Patient/Parent/Legal Guardian-Physician Agreement Form* indicating that he/she has:
 - i) [Been provided and has read the *What You Need to Know About SABRIL Treatment: A Patient Guide*](#);
 - ii) Been counseled by the prescriber regarding the risk of vision loss; and
 - iii) Been counseled by the prescriber regarding the need for periodic visual monitoring, including ophthalmologic assessments, based on the recommendations in the Prescribing Information.

b) Lundbeck will:

- i) Ensure that the certified prescriber is able to submit the completed *SABRIL REMS Program Patient/Parent/Legal Guardian-Physician Agreement Form* to the SABRIL REMS Program online, by fax, or by mail.

Ensure that the certified pharmacy completes the verifications required under section 2 for each patient prior to dispensing. The following materials are part of the SABRIL REMS Program and are appended:

- *What You Need to Know About SABRIL Treatment: A Patient Guide;*
- *SABRIL REMS Program Patient/Parent/Legal Guardian-Physician Agreement Form.*

B. Implementation System

1. Lundbeck must send a one-time *SABRIL REMS Program Letter for Eye Care Professionals* within 30 calendar days of the approval of the SABRIL REMS Program modification (June 2016). The *SABRIL REMS Program Letter for Eye Care Professionals* will address the risk of visual loss and changes which have occurred to the SABRIL REMS Program. SABRIL REMS Program Letters will be distributed by email. See Section **A(1)(c) (ix)** for distribution information.
 - a. **SABRIL REMS Program Letter for Eye Care Professionals:** The intended audience for the *SABRIL REMS Program Letter for Eye Care Professionals* will be optometrists and ophthalmologists as well as the following professional societies and organizations, in which Lundbeck requests the letter be provided to their membership. The following materials will be appended to the letter: *Prescribing Information* and *SABRIL REMS Program Fact Sheet for Eye Care Professionals*
 - b. Targeted eye care societies include the following:
 - i. American Academy of Ophthalmology
 - ii. American Academy of Optometry
 - iii. American Association for Pediatric Ophthalmology and Strabismus
 - iv. American Board of Ophthalmology
 - v. American Optometric Association
2. Lundbeck must ensure that SABRIL is only distributed to certified pharmacies.
3. Lundbeck must maintain a validated, secure database of health care professionals certified to prescribe SABRIL, pharmacies who are certified to dispense SABRIL and patients enrolled in the SABRIL REMS Program.
4. Lundbeck must ensure that the pharmacies meet the SABRIL REMS Program certification requirements and may de-certify non-compliant pharmacies who do not maintain compliance with certification requirements.

5. Lundbeck must maintain a SABRIL REMS Program Call Center (888-457-4273) and SABRIL REMS Program Website [www.SabrilREMS.com]. The REMS Program Website will include the option to print the PI, Medication Guide, and SABRIL REMS Program materials. The SABRIL product website will include a prominent SABRIL REMS Program-specific link to the SABRIL REMS Program Website. The SABRIL REMS Program website will be available within 30 calendar days of the approval of the SABRIL REMS Program modification (June 2016) and the online certification functionality will be available 180 calendar days after the approval of the SABRIL REMS Program modification (June 2016).
6. Lundbeck must ensure that within 30 calendar days after approval of this SABRIL REMS Program modification (June 2016) the SABRIL REMS Program materials listed in or appended to the SABRIL REMS Program document are available through the SABRIL REMS Program Website or can be accessed by calling the SABRIL REMS Program.
7. Lundbeck must monitor and audit each certified pharmacy within 90 calendar days after the pharmacy is certified to ensure that all processes and procedures are in place and functioning to support the requirements of the SABRIL REMS Program. The certified pharmacies will also be included in Lundbeck's ongoing annual audit plan. Corrective action will be instituted by Lundbeck if noncompliance is identified.
8. Lundbeck must take reasonable steps to improve implementation of and compliance with the requirements of the SABRIL REMS Program based on monitoring and evaluation of the SABRIL REMS Program.

The following materials are part of the-SABRIL REMS Program and are appended:

- *SABRIL REMS Program Letter for Eye Care Professionals*
- *SABRIL REMS Program Fact Sheet for Eye Care Professionals*
- *SABRIL REMS Program Website*

C. Timetable for Submission of Assessments

Lundbeck will submit SABRIL REMS Program assessments to the FDA annually from the date of the approval of the SABRIL REMS Program modification (June 21, 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. Lundbeck will submit each assessment so that it will be received by the FDA on or before the due date.