

SABRIL REMS Program Changes For Pharmacies

- **Outpatient Pharmacies must re-certify by September 19, 2016**
- **Inpatient Pharmacies can now enroll**

Dear Pharmacist:

The purpose of this letter is to inform you of recent changes in the SABRIL® (vigabatrin) Risk Evaluation and Mitigation Strategy (REMS) Program formerly called the SHARE Program. In order to continue to dispense SABRIL, **pharmacies must take action** to meet the SABRIL REMS Program requirements.

Changes to the SABRIL REMS Program for Pharmacists

1. **All currently enrolled pharmacies must re-certify by completing and submitting a *SABRIL REMS Program Pharmacy Enrollment Form* to the SABRIL REMS Program by September 19, 2016.**
2. **Inpatient pharmacies can now enroll in the SABRIL REMS Program to dispense SABRIL in their healthcare facility.**

Pharmacies will need to meet the following requirements in order to dispense SABRIL:

- Designate an authorized representative to complete enrollment by submitting the *SABRIL REMS Program Pharmacy Enrollment Form*.
- Ensure the authorized representative oversees implementation and compliance with the SABRIL REMS Program requirements:
 - **Training:** Ensure that all relevant staff involved in the dispensing of SABRIL are trained on the SABRIL REMS Program requirements.
 - **Verification:** Before dispensing SABRIL to a patient, verify that the prescriber is certified and the patient has been enrolled in the SABRIL REMS Program. You can verify enrollment by going to the SABRIL REMS Program website at www.SabrilREMS.com.
 - **Compliance:** Comply with requests to be audited by Lundbeck, FDA, and/or a third party.
 - **Inpatient pharmacies only:** Ensure that the pharmacy does not dispense more than a 15-day temporary supply of SABRIL upon discharge from the healthcare facility.

Other Changes to the SABRIL REMS Program

- Vision testing is recommended, but drug shipment is no longer contingent upon completion of this testing.
- Pharmacists no longer need to obtain a dispensing authorization number prior to filling a SABRIL prescription.
- Certified inpatient pharmacies may now stock SABRIL for treatment of infantile spasms and refractory complex partial seizures patients.

De-certification may occur if there is non-compliance with these REMS requirements.

How To Enroll or Re-Certify in the SABRIL REMS Program

- Visit www.SabrilREMS.com and download the *SABRIL REMS Program Pharmacy Enrollment Form*; or
- Call the SABRIL REMS Program at 1-888-457-4273.

Indication

SABRIL is approved by the Food and Drug Administration (FDA) for the following indications: SABRIL is indicated as adjunctive therapy for adults and pediatric patients 10 years of age and older with refractory complex partial seizures (CPS) who have inadequately responded to several alternative treatments and for whom the potential benefits outweigh the risk of vision loss. SABRIL is not indicated as a first line agent for complex partial seizures. In addition, SABRIL is indicated as monotherapy for pediatric patients with infantile spasms (IS) 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss.

Please see the accompanying [Prescribing Information](#) and [Medication Guide](#) for your reference.

For more detail on the new SABRIL REMS Program, please visit www.SabrilREMS.com.

As always, please report any adverse events to Lundbeck at 1-800-455-1141 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Sincerely,

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