

SABRIL REMS PROGRAM CHANGES EFFECTIVE June 2016

Dear Healthcare Professional:

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, as you may treat these patients and need to be aware of the **changes in vision assessment requirements**. We also want to remind you of the risk of permanent vision loss associated with SABRIL and the importance of regular ophthalmologic assessments to help mitigate this risk.

Changes to the SABRIL REMS Program for Prescribers

1. **All currently enrolled prescribers will need to recertify by completing and submitting a *SABRIL REMS Program Prescriber Enrollment and Agreement Form (PEAF)* to the SABRIL REMS Program by September 19, 2016.**
2. Prescribers will no longer need to complete a Treatment Initiation Form (TIF), Treatment Maintenance Form (TMF) or an Ophthalmologic Assessment Form (OAF).
3. Prescriptions may now be submitted directly to Certified Specialty Pharmacies enrolled in the SABRIL REMS Program or you may continue to submit them to the SABRIL REMS Program.
4. All forms can be accessed at www.SabrILREMS.com and can be faxed to 1-877-742-1002.

As of June 2016, prescribers will need to meet the following requirements in order to prescribe SABRIL:

- **Review** the SABRIL Prescribing Information and complete and submit the *SABRIL REMS Program PEA Form* to the SABRIL REMS Program.
- **Enroll** each patient in the SABRIL REMS Program by counseling the patient/caregiver about the risks associated with SABRIL, including permanent vision loss and need for periodic vision monitoring.
- **Provide** each patient a copy of *What You Need to Know About SABRIL Treatment: A Patient Guide*.
- **Complete** the *SABRIL REMS Program Patient/Parent/Legal Guardian-Physician Agreement Form* for each patient, submit it to the SABRIL REMS Program, keep a copy in the patient's records, and provide a copy to the patient/caregiver.
- **Ensure** that periodic vision monitoring, as described in the Prescribing Information, is performed on an ongoing basis for each patient.
- **Report** any adverse event suggestive of vision loss to the SABRIL REMS Program with all available information.

Risk of Permanent Vision Loss with SABRIL

SABRIL can cause permanent vision loss. Because of this risk and because, when it is effective, SABRIL provides an observable symptomatic benefit, patient response and continued need for treatment should be periodically assessed.

Based upon adult studies, 30 percent or more of patients can be affected with bilateral, concentric visual field constriction, ranging in severity from mild to severe. Severe cases may be characterized by tunnel vision to within 10 degrees of visual fixation, which can result in disability. In some cases, SABRIL may also decrease visual acuity. The onset of vision loss from SABRIL is unpredictable, and can occur

within weeks of starting treatment or sooner, or at any time after starting treatment, even after months or years. The risk of vision loss increases with increasing dose and cumulative exposure, but there is no dose or exposure known to be free of the risk of vision loss. The possibility that vision loss can worsen despite discontinuation of SABRIL has not been excluded.

Because of the risk of vision loss:

- SABRIL should be withdrawn from adult patients with refractory complex partial seizures (CPS) who fail to show substantial clinical benefit within 3 months of initiation, or sooner if treatment failure becomes obvious.
- SABRIL should be withdrawn from patients with infantile spasms who fail to show substantial clinical benefit within 2 to 4 weeks of initiation, or sooner if treatment failure becomes obvious.

Importance of Ophthalmologic Assessments While on SABRIL

Symptoms of vision loss from SABRIL are unlikely to be recognized by patients or caregivers before vision loss is severe; therefore, appropriate vision monitoring is needed. Once detected, vision loss due to SABRIL is not reversible. It is expected that, even with frequent monitoring, some patients will develop severe vision loss. Monitoring of vision by an ophthalmic professional (defined as having expertise in visual field interpretation and the ability to perform dilated indirect ophthalmoscopy of the retina) is recommended.

Vision monitoring is recommended in patients receiving SABRIL at baseline (no later than 4 weeks after starting SABRIL) and at least every 3 months while on therapy. Vision testing is also recommended about 3 to 6 months after the discontinuation of SABRIL therapy.

Indication

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,

Alina M. Fernández, MD, MPH, MBA
VP, Global Pharmacovigilance-US, Lundbeck

Adam Ziemann, MD, PhD
Director, US Clinical Research, Neurology, Lundbeck

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