

SABRIL REMS PROGRAM CHANGES EFFECTIVE June 2016

Dear Eye Care 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 conduct vision testing on 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 Eye Care Professionals

The following changes specific to eye care professionals are effective immediately:

1. **Eye care professionals will no longer need to complete an Ophthalmologic Assessment Form (OAF).**
2. Periodic vision testing is recommended as described in the accompanying [SABRIL REMS Program Fact Sheet for Eye Care Professionals](#).
3. Drug shipment is no longer contingent upon completion of this testing.

As of June 2016, eye care professionals should meet the following vision monitoring recommendations for patients on SABRIL:

- **Tailor** the diagnostic approach for each patient and the clinical situation
- **Assess** each patient's visual acuity and visual fields, if possible. However, no specific tests are required.
- **Recommend** perimetry, preferably by automated threshold visual field testing, in adults and children 10 years and older.
- **Consider** additional testing options such as electrophysiology (e.g., electroretinography [ERG]), retinal imaging (e.g., optical coherence tomography [OCT]), indirect ophthalmoscopy/fundoscopy in appropriate patients.
- **Interpret** results from ophthalmic monitoring with caution, as reliability and predictive value are variable.
- **Repeat** testing in the first few weeks of treatment to establish if reproducible results can be obtained, and to guide selection of appropriate ongoing monitoring for the patient.
- **Report** any adverse event suggestive of vision loss to the SABRIL REMS Program with all available information (888-457-4273).

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.

Monitoring of vision, including assessment of visual fields and visual acuity, is recommended at baseline (no later than 4 weeks after starting SABRIL), at least every 3 months while on therapy, and about 3-6 months after discontinuation of therapy.

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.

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](#), [Medication Guide](#), and a [SABRIL REMS Program Fact Sheet for Eye Care Professionals](#) 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