

**Lundbeck**

Six Parkway North Deerfield, IL 60015, USA  
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www.lundbeck.com/us



**IMPORTANT DRUG WARNING**  
**SABRIL® (VIGABATRIN) Tablets**  
**SABRIL® (VIGABATRIN) Powder for Oral Solution**

October 24, 2019

**Neurotoxicity (Intramyelinic Edema) Reported With Use of Sabril**

Dear Healthcare Professional,

The purpose of this letter is to inform you of important new safety information for Sabril® (vigabatrin). Sabril was initially approved in 2009 and currently approved as adjunctive therapy for adults and pediatric patients 10 years of age and older with refractory complex partial seizures who have inadequately responded to several alternative treatments and as monotherapy for pediatric patients with infantile spasms 1 month to 2 years of age. Cumulatively through August 20, 2019, the total number of patient treatment days is estimated to be 20.5 million corresponding to 56,124 PY within the United States, Canada and Mexico.

**New Safety Information with Use of Sabril: Neurotoxicity**

There have been literature reports of intramyelinic edema (IME) diagnosed by postmortem brain examination in pediatric patients treated with Sabril. One report involved a 10-month old infant, treated with Sabril for 2 weeks who died of bronchopneumonia. A second report involved a 27-month-old patient treated with Sabril for 23 months who died of Sudden Unexplained Death in Epilepsy (SUDEP) during a period of seizure control. While the patients in these two cases were being treated with Sabril, a causal relationship between the use of Sabril and IME in humans has not been fully established.

IME observed in animals is described in the prescribing information under Warnings and Precautions. As per the labeling approved by FDA on July 31, 2019, Lundbeck updated this section to include the following new statement which reflects the observation of IME in humans:

*“Intramyelinic edema (IME) has been reported in postmortem examination of infants being treated for infantile spasms (IS) with vigabatrin.”*

**Prescriber Action**

Counsel patients about the risks and benefits of Sabril, including the reports of IME. Tell your patients and/or caregivers to contact a healthcare professional immediately to report any change in the neurological status or developmental progress of the patient.

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**Reporting Adverse Events**

Healthcare professionals, caregivers and patients are encouraged to report adverse events in patients taking Sabril to Lundbeck at 1-800-455-1141 or [luinc\\_safety@lundbeck.com](mailto:luinc_safety@lundbeck.com). You are encouraged to report side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

You may also contact Lundbeck's Medical Information Department at 1-866-402-8520 or [medicalinformation@lundbeck.com](mailto:medicalinformation@lundbeck.com) if you have any questions about the information contained in this letter or the safe and effective use of Sabril.

This letter is not intended as a complete description of the benefits and risks related to the use of Sabril. Please refer to the enclosed Prescribing Information and Medication Guide.

Sincerely,

A handwritten signature in black ink, appearing to be "DW" followed by a long horizontal stroke.

Doug Williamson  
Chief Medical Officer, VP US Medical  
Lundbeck