



This page from the Epilepsy Foundation website can be viewed at:

<http://www.epilepsyfoundation.org/epilepsyusa/news/Sabril-Approved-by-FDA-to-Treat-Spasms-in-Infants-and-Epileptic-Seizures.cfm>

Sabril Approved by FDA to Treat Spasms in Infants and Epileptic Seizures

Sabril (vigabatrin) oral solution has been approved by the Food and Drug Administration to treat [infantile spasms](#) in children ages 1 month to 2 years. Sabril is the first drug in the United States approved to treat the disorder, characterized by a severe type of seizure that usually appears in the first year of life, typically between ages 4 months and 8 months. The disorder can be debilitating because of the frequency of difficult-to-control daily seizures.

Sabril (vigabatrin) tablets have been approved for adult use in combination with other medications to treat complex partial seizures that have not responded adequately to previous drug therapies.

“Seizures can cause impaired nervous system function and reduced quality of life,” said Russell Katz, M.D., director of the Division of Neurology Products at the FDA’s Center for Drug Evaluation and Research. “Infantile spasms in children this young are very serious and this approval provides these patients and their parents a treatment option.”

Infantile spasms consist primarily of a sudden bending forward of the body with stiffening of the arms and legs; some children arch their backs as they extend their arms and legs. Spasms tend to occur upon awakening or after feeding, and often occur in clusters of up to 100 spasms. Infants may have dozens of clusters and several hundred spasms per day. Many underlying disorders, such as birth injury, metabolic disorders and genetic disorders can give rise to spasms, making it important to identify the underlying cause. In some children, no cause can be found.

Epilepsy is a neurological condition that produces disturbances in the normal electrical functions of the brain, causing people to have recurring seizures. Seizures happen when nerve cells, or neurons, in the brain send out the wrong signals. People may have strange sensations and emotions or behave strangely. They may have violent muscle jerking, which may be repetitive, or lose consciousness.

Damage to vision is an important safety concern with the use of Sabril. The drug will have a boxed warning to alert health care professionals to this risk of a progressive loss of peripheral vision with potential decrease in visual acuity. The risk of vision damage may increase based on the dosage and duration of use, but even the lowest doses of Sabril can cause vision damage. Periodic vision testing is required for those taking Sabril. Because of the risk of permanent vision damage, the drug will be available only through a restricted distribution program.

Sabril was designated as an orphan drug by the FDA for use in treating infantile spasms. A drug is eligible for orphan drug designation if it is intended to treat a disease or condition that affects fewer than 200,000 people in the United States. Orphan drug status provides the company with financial incentives to promote the development of a drug to treat a rare disease or condition.

Sabril is made by Lundbeck Inc. of, Deerfield, Ill. Read Lundbeck’s press release on the approval of Sabril [here](#).

Source: FDA press release.