

Sabril[®] (vigabatrin) – Expanded indication

- On January 24, 2020, the [FDA approved](#) Lundbeck's [Sabril \(vigabatrin\)](#), as adjunctive therapy for adults and pediatric patients 2 years of age and older with refractory complex partial seizures who have inadequately responded to several alternative treatments and for whom the potential benefits outweigh the risk of vision loss.
 - Sabril was previously approved for this indication in patients 10 years of age and older.
 - Sabril is not indicated as a first line agent for complex partial seizures.
- Sabril is also approved as monotherapy for pediatric patients with infantile spasms 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss.
- The safety and effectiveness of Sabril as adjunctive treatment of refractory complex partial seizures in pediatric patients 2 to 16 years of age have been established and is supported by three double-blind, placebo-controlled studies in patients 3 to 16 years of age, adequate and well-controlled studies in adult patients, pharmacokinetic data from patients 2 years of age and older, and additional safety information in patients 2 years of age.
- Sabril carries a boxed warning for permanent vision loss.
- The recommended dose of Sabril for the treatment of refractory complex partial seizures in pediatric patients (2 to 16 years of age) is based on body weight and administered as two divided doses. The dosage may be increased in weekly intervals to the total daily maintenance dosage, depending on response.

Body weight (kg)	Total daily starting dose (mg/day)	Total daily maintenance dose (mg/day)
10 kg to 15 kg	350 mg	1050 mg
> 15 kg to 20 kg	450 mg	1300 mg
> 20 kg to 25 kg	500 mg	1500 mg
> 25 kg to 60 kg	500 mg	2000 mg

- Sabril should be withdrawn if a substantial clinical benefit is not observed within 3 months of initiating treatment. If, in the clinical judgment of the prescriber, evidence of treatment failure becomes obvious earlier than 3 months, treatment should be discontinued at that time.
- Refer to the Sabril drug label for dosing in adults and for its other indication.