

Vimpat® (lacosamide) - Expanded indication

- On November 6, 2017, <u>UCB announced</u> the FDA approval of <u>Vimpat (lacosamide)</u> tablets and oral solution, for the treatment of partial-onset seizures in patients 4 years of age and older.
 - Previously, Vimpat was indicated in patients 17 years and older with partial-onset seizures as monotherapy or adjunctive therapy.
 - As the safety of Vimpat injection in pediatric patients has not been established, Vimpat injection is indicated for the treatment of partial-onset seizures only in adult patients (17 years of age and older).
 - Vimpat is a Schedule V controlled substance (C-V).
- According to the <u>Centers for Disease Control and Prevention</u>, in the U.S., about 0.6% of children aged 0 17 years have active epilepsy.
- The safety and effectiveness of Vimpat tablets and oral solution have been established in pediatric patients 4 to less than 17 years of age.
 - Use of Vimpat in this age group is supported by evidence from adequate and well-controlled studies of Vimpat in adults with partial-onset seizures, pharmacokinetic data from adult and pediatric patients, and safety data in 328 pediatric patients 4 to less than 17 years of age.
- Adverse reactions reported in clinical studies of pediatric patients 4 to less than 17 years of age were similar to those seen in adult patients.
- The recommended dosage of Vimpat tablets and oral solution in pediatric patients is based on body weight and is administered orally twice daily.

Age and Body Weight	Initial Dosage	Maintenance Dosage
Pediatric patients weighing ≥ 50 kg	50 mg twice daily	Monotherapy: 150 – 200 mg twice daily
		Adjunctive Therapy: 100 – 200 mg twice daily
Pediatric patients weighing 30 kg to < 50 kg	1 mg/kg twice daily	2 – 4 mg/kg twice daily
Pediatric patients weighing 11 kg to < 30 kg	1 mg/kg twice daily	3 – 6 mg/kg twice daily

 Dosage should be increased based on clinical response and tolerability, no more frequently than once per week.

Consult the Vimpat drug label for detailed dosing recommendations for adult patients.



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