



## Briviact® (brivaracetam) – Expanded indication

- On August 30, 2021, [UCB announced](#) the FDA approval of [Briviact \(brivaracetam\)](#), for the treatment of partial-onset seizures in patients 1 month of age and older.
  - Oral formulations of Briviact were previously approved for this indication for patients 4 years of age and older.
  - Briviact injection was previously approved for this indication only in adult patients (16 years of age and older).
- The approval of Briviact for the expanded indication was supported by evidence from adequate and well-controlled studies of Briviact in adults with partial-onset seizures, pharmacokinetic data from adult and pediatric patients, and safety data in pediatric patients 2 months to less than 16 years of age.
- Briviact is a schedule V controlled substance.
- The recommended dosage for Briviact for patients 1 month of age and older is provided in the table below. In pediatric patients weighing less than 50 kg, the recommended dosing regimen is dependent upon body weight.
  - Dosage should be adjusted based on clinical response and tolerability.
  - Briviact injection may be used when oral administration is temporarily not feasible.
  - Briviact injection should be administered intravenously at the same dosage and same frequency as Briviact tablets and oral solution. The clinical study experience with Briviact injection is up to 4 consecutive days of treatment.

Age and body weight	Initial dosage	Minimum and maximum maintenance dosage
Adults (16 years and older)	50 mg twice daily (100 mg per day)	25 mg to 100 mg twice daily (50 mg to 200 mg per day)
Pediatric patients weighing 50 kg or more	25 mg to 50 mg twice daily (50 mg to 100 mg per day)	25 mg to 100 mg twice daily (50 mg to 200 mg per day)
Pediatric patients weighing 20 kg to less than 50 kg	0.5 mg/kg to 1 mg/kg twice daily (1 mg/kg to 2 mg/kg per day)	0.5 mg/kg to 2 mg/kg twice daily (1 mg/kg to 4 mg/kg per day)
Pediatric patients weighing 11 kg to less than 20 kg	0.5 mg/kg to 1.25 mg/kg twice daily (1 mg/kg to 2.5 mg/kg per day)	0.5 mg/kg to 2.5 mg/kg twice daily (1 mg/kg to 5 mg/kg per day)
Pediatric patients weighing less than 11 kg	0.75 mg/kg to 1.5 mg/kg twice daily (1.5 mg/kg to 3 mg/kg per day)	0.75 mg/kg to 3 mg/kg twice daily (1.5 mg/kg to 6 mg/kg per day)



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