

Lyrica® (pregabalin) – Expanded indication

- On May 3, 2018, the FDA approved Pfizer’s [Lyrica \(pregabalin\)](#), for adjunctive therapy for the treatment of partial onset seizures in patients 4 years of age and older.
 - Previously, Lyrica was approved as adjunctive therapy for adult patients with partial onset seizures.
- Lyrica is also approved to treat neuropathic pain associated with diabetic peripheral neuropathy, postherpetic neuralgia, fibromyalgia, and neuropathic pain associated with spinal cord injury.
- The efficacy of Lyrica as adjunctive therapy in partial onset seizures was demonstrated in a 12-week, placebo-controlled study in 294 pediatric patients 4 years to less than 17 years of age with partial onset seizures with or without secondary generalization. Patients received 2.5 mg/kg/day of Lyrica (adjusted for patients weighing < 30 kg; maximum dose of 150 mg/day), 10 mg/kg/day of Lyrica (adjusted for patients weighing < 30 kg; maximum dose of 600 mg/day), or placebo.
 - Median percentage change from baseline in seizure rates were -16.9% for placebo, -27.3% for Lyrica 2.5 mg/kg/day (percentage difference vs. placebo: -10.5%; p = 0.2577), and -37.1% for Lyrica 10 mg/kg/day (percentage difference vs. placebo: -21.0%; p = 0.0185).
 - Only the 10 mg/kg/day dose of Lyrica achieved a statistically significant difference vs. placebo.
- In pediatric patients with partial onset seizures, the most common adverse reactions (≥ 5%) with Lyrica use were increased weight and increased appetite.
- The recommended dosage for pediatric patients 4 years to < 17 years for partial onset seizures is dependent upon body weight (see table below). For adult and pediatric patients, administer the total daily dose orally in two or three divided doses.

Age and Body Weight	Recommended Initial Dose	Maximum Recommended Dose
Adults (17 years and older)	150 mg/day	600 mg/day
Pediatric patients weighing ≥ 30 kg	2.5 mg/kg/day	10 mg/kg/day (not to exceed 600 mg/day)
Pediatric patients weighing 11 to < 30 kg	3.5 mg/kg/day	14 mg/kg/day

- Based on clinical response and tolerability, dosage may be increased, approximately weekly.
- Consult the Lyrica drug label for dosing recommendations for other indications.