

Briviact® (brivaracetam) – Expanded indication

- On September 15, 2017, [UCB announced](#) the FDA approval of [Briviact \(brivaracetam\)](#) injection, tablets and oral solution, for the treatment of partial-onset seizures (POS) in patients 16 years of age and older with epilepsy.
 - Previously, Briviact was indicated as adjunctive therapy in the treatment of POS in patients 16 years of age and older with epilepsy.
- The expanded indication for Briviact was supported by a recent General Advice Letter, issued by the FDA, which stated it is acceptable to extrapolate the efficacy and safety of drugs approved as adjunctive therapy for the treatment of POS to their use as monotherapy for the treatment of POS.
 - UCB was able to support its Briviact monotherapy submission with clinical trials data, which involved more than 2,400 adult patients with POS.
- The recommended dosage of Briviact for monotherapy or adjunctive therapy of POS is 50 mg orally twice daily. Based on individual patient tolerability and therapeutic response, the oral dosage may be adjusted down to 25 mg twice daily or up to 100 mg twice daily.
 - Briviact injection may be used when oral administration is temporarily not feasible. Briviact injection should be administered at the same dosage and same frequency as Briviact tablets and oral solution.