



## Qudexy<sup>®</sup> XR (topiramate) – New indication

- On March 30, 2017, [Upsher-Smith announced](#) the [FDA approval](#) of [Qudexy XR \(topiramate\)](#) extended-release capsules, for the prophylaxis of migraine headache in adults and adolescents 12 years of age and older.
  - The usefulness of Qudexy XR in the acute treatment of migraine headache has not been studied.
- Qudexy XR is also approved for initial monotherapy and adjunctive therapy in patients 2 years and older with partial onset or primary generalized tonic-clonic seizures, and for adjunctive therapy in patients 2 years of age and older with seizures associated with Lennox-Gastaut syndrome.
- Qudexy XR's new indication approval was based on data from 2 double-blind, placebo-controlled trials enrolling 937 patients with a history of migraine, with or without aura. Patients received immediate-release topiramate 50 mg/day, 100 mg/day, 200 mg/day or placebo for 26-weeks. Effectiveness of treatment was assessed by the reduction in migraine headache frequency, as measured by the change in 4-week migraine rate.
  - In both trials, the treatment differences between the topiramate 100 and 200 mg/day groups vs. placebo were similar and statistically significant.
  - Furthermore, in a separate trial in adolescent patients (12 – 17 years old) with a history of episodic migraines with or without aura, topiramate 100 mg achieved a 28% reduction from baseline in the monthly migraine attack rate over placebo ( $p = 0.0164$ ).
  - The pharmacokinetic equivalence of Qudexy XR to immediate-release topiramate has been demonstrated in clinical studies.
- The recommended dose of Qudexy XR for the prevention of migraine headache is 100 mg orally once daily.
  - The Qudexy XR dose should be titrated starting with 25 mg/day for week 1, 50 mg/day for week 2, 75 mg/day for week 3, and 100 mg/day for week 4 and beyond.
  - The dose and titration rate should be guided by clinical outcome. If required, longer intervals between dose adjustments may be used.
  - The capsules may be opened and the contents sprinkled onto a small amount of soft food, which may be helpful to patients who have difficulty swallowing whole capsules.
- Consult Qudexy XR's drug label for the recommended doses for the other indications.



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