Motpoly XR (lacosamide) – New drug approval

- On May 4, 2023, the FDA approved Acute Pharmaceuticals' Motpoly XR (lacosamide), for the treatment of partial-onset seizures in adults and in pediatric patients weighing at least 50 kg.

- Motpoly XR is an extended-release formulation of lacosamide. Immediate-release lacosamide is available under the brand name Vimpat® in an oral tablet, oral solution, and injection formulation.

    — Vimpat is approved for the treatment of partial-onset seizures in patients 1 month of age and older and adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients 4 years of age and older.
    — Generic alternatives to Vimpat are available but due to marketing exclusivity rights for Vimpat, these drugs have narrower indications. Refer to the generic drug labels for the specific indication approvals.

- The efficacy of Motpoly XR is based on the relative bioavailability of Motpoly XR compared to immediate-release lacosamide in healthy adults.

- Warnings and precautions for Motpoly XR include suicidal behavior and ideation; dizziness and ataxia; cardiac rhythm and conduction abnormalities; syncope; withdrawal of antiepileptic drugs; drug reaction with eosinophilia and systemic symptoms (DRESS)/multi-organ hypersensitivity.

- The most common adverse reactions (≥ 10% and greater than placebo) with Motpoly XR adjunctive therapy in adults are diplopia, headache, dizziness, nausea, and somnolence.

    — The most common adverse reactions with Motpoly XR monotherapy are similar to those seen in adjunctive therapy studies.
    — The adverse reactions with Motpoly XR use in pediatric patients are similar to those seen in adult patients.

- The recommended dosage for monotherapy and adjunctive therapy for partial-onset seizures in adults and in pediatric patients weighing at least 50 kg is included in the table below.

    — Dosage should be increased based on clinical response and tolerability, no more frequently than once per week.
    — In adjunctive clinical trials in adult patients with partial-onset seizures, a dosage higher than 400 mg per day was not more effective and was associated with a substantially higher rate of adverse reactions.

Age and body weight	Initial dosage	Titration regimen	Maintenance dosage
Adults (≥ 17 years)	Monotherapy: 200 mg once daily Adjunctive therapy: 100 mg once daily	Increase by 100 mg once daily every week	Monotherapy: 300 mg to 400 mg once daily Adjunctive Therapy: 200 mg to 400 mg once daily
Pediatric patients weighing ≥ 50 kg	100 mg once daily	Increase by 100 mg once daily every week	Monotherapy: 300 mg to 400 mg once daily

Continued . . .

			Adjunctive Therapy: 200 mg to 400 mg once daily

- Aucta Pharmaceuticals' launch plans for Motpoly XR are pending. Motpoly XR will be available as 100 mg, 150 mg, 200 mg extended-release capsules.