FIRST TIME GENERIC APPROVAL

Brand Name	Vimpat®
Generic Name	lacosamide
Drug Manufacturer	ALKEM LABS LTD

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic

FDA APPROVAL DATE

March 12, 2021

LAUNCH DATE

N/A

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 214672

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Lacosamide oral solution is indicated for:

- Treatment of partial-onset seizures in patients 4 years of age and older.
- Adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients 4 years of age and older.

MECHANISMS OF ACTION

The precise mechanism by which lacosamide exerts its antiepileptic effects in humans remains to be fully elucidated. In vitro electrophysiological studies have shown that lacosamide selectively enhances slow inactivation of voltage-gated sodium channels, resulting in stabilization of hyperexcitable neuronal membranes and inhibition of repetitive neuronal firing.

DOSE FORM AND STRENGTH

10 mg/mL oral solution.

DOSE & ADMINISTRATION

- Adults (17 years and older)
  - Initial dosage for monotherapy for the treatment of partialonset seizures is 100 mg twice daily.

  - Initial dosage for adjunctive therapy for the treatment of partial-onset seizures or primary generalized tonic-clonic seizures is 50 mg twice daily.
  - Maximum recommended dosage for monotherapy and adjunctive therapy is 200 mg twice daily.
- Pediatric Patients 4 years to less than 17 years: The recommended dosage is based on body weight and is administered orally twice daily.
  - Pediatric Patients 4 years to less than 17 years: The recommended dosage is based on body weight and is administered orally twice daily.