FIRST TIME GENERIC APPROVAL

Brand Name	Banzel®
Generic Name	rufinamide
Drug Manufacturer	Hikma Pharmaceuticals USA Inc.

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic Approval

FDA APPROVAL DATE

May 16, 2016

LAUNCH DATE

November 4, 2020

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 204988

DISPENSING RESTRICTIONS

Specialty

Overview

INDICATION FOR USE

It is indicated for adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in pediatric patients 1 year of age and older and in adults.

MECHANISMS OF ACTION

The precise mechanism(s) by which rufinamide exerts its antiepileptic effect is unknown.

The results of in vitro studies suggest that the principal mechanism of action of rufinamide is modulation of the activity of sodium channels and, in particular, prolongation of the inactive state of the channel. Rufinamide (≥1 mcM) significantly slowed sodium channel recovery from inactivation after a prolonged prepulse in cultured cortical neurons, and limited sustained repetitive firing of sodium-dependent action potentials (EC50 of 3.8 mcM).

DOSE FORM AND STRENGTH

Oral suspension: 40 mg/mL, packaged with two 20 mL syringes and one press in bottle adapter (PIBA)

DOSE & ADMINISTRATION

Rufinamide should be given with food.
Measure oral suspension using provided adapter and dosing syringe.

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Pediatric Patients 1 Year and Older:

- Starting daily dose: 10 mg/kg per day in two equally divided doses
- Increase by 10 mg/kg increments every other day to maximum dose of 45 mg/kg per day, not to exceed 3200 mg per day, in two divided doses.

Adults:

- Starting daily dose: 400 to 800 mg per day in two equally divided doses.
- Increase by 400 to 800 mg every other day until a maximum dose of 3200 mg per day, in two divided doses, is reached.