Indication

- BANZEL 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.

Important Safety Information

Contraindication:

- BANZEL is contraindicated in patients with Familial Short QT syndrome.

Warnings and Precautions:

- Suicidal behavior and ideation: AEDs increase the risk of suicidal thoughts or behavior in patients. Patients, their caregivers, and families should be informed of the risk and advised to monitor and report any emergence or worsening of depression, suicidal thoughts or behavior, or any unusual changes in mood or behavior, or thoughts of self-harm. If these symptoms occur, consider if it may be related to the AED or illness because epilepsy itself can increase these risks.
- Central nervous system reactions: Use of BANZEL has been associated with central nervous system–related adverse reactions, such as somnolence or fatigue, coordination abnormalities, dizziness, gait disturbances, and ataxia.
- QT shortening: Formal cardiac ECG studies demonstrated shortening of the QT interval (mean = 20 msec, for doses ≥ 2400 mg twice daily) with BANZEL. Caution should be used when administering BANZEL with other drugs that shorten the QT interval.
- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS): Multi-organ hypersensitivity syndrome, also known as DRESS, has been reported in association with BANZEL therapy. In clinical trials, hypersensitivity reactions occurred in children less than 12 years of age and within 4 weeks of starting BANZEL therapy. In addition, rare cases of DRESS and Stevens-Johnson syndrome have been reported in association with rufinamide therapy post marketing. If any of these reactions are suspected, BANZEL should be discontinued and alternative treatment started. All patients who develop a rash while taking BANZEL must be closely supervised.
- Withdrawal of AEDs: As with all AEDs, BANZEL should be gradually withdrawn to minimize the risk of increased seizure frequency.

Adverse reactions:

- In the pooled, double-blind, adjunctive therapy studies in adults and pediatric patients ages 3 and older, the most commonly observed (≥10%) adverse reactions with BANZEL vs placebo, respectively, were headache (25% vs 20%),

dizziness (17% vs 10%), fatigue (15% vs 9%), somnolence (12% vs 9%), and nausea (11% vs 7%).

- In a multicenter, parallel group, open-label study in pediatric patients (1 year to less than 4 years of age) the most commonly observed (≥10%) adverse reactions and with a higher frequency with BANZEL vs any other AED, respectively, were vomiting (24% vs 9%), somnolence (16% vs 0%), constipation (12% vs 9%), cough (12% vs 9%), bronchitis (12% vs 0%), rash (12% vs 9%), and decreased appetite (12% vs 9%).