

**Department of Health and Human Services
Public Health Service**

**Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
BPCA Drug Utilization Review**

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Product Name(s): Banzel™ (rufinamide)

**Last Pediatric Labeling
Approval Date:** 2/12/2015

Application Type/Number: NDA #21911 (oral tablets) and
#201367 (oral suspension)

Applicant/sponsor: Eisai

OSE RCM #: 2017-1002

****This document contains proprietary drug use data obtained by FDA under contract. The drug use data/information cannot be released to the public/non-FDA personnel without contractor approval obtained through the FDA/CDER Office of Surveillance and Epidemiology.****

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1 INTRODUCTION

In accordance with the Food and Drug Administration Amendments Act (FDAAA) Pediatric Research Equity Act (PREA), Division of Epidemiology (DEPI) II in the Office of Surveillance and Epidemiology (OSE) provides recent drug utilization data for Banzel (rufinamide) in pediatric patients.

1.1 PEDIATRIC REGULATORY HISTORY

FDA first approved rufinamide oral tablets on 11/14/2008 and subsequently approved rufinamide oral suspension on 3/3/2011 for adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in pediatric patient 4 years and older and in adults. FDA approved rufinamide (oral tablets and oral suspension) on 2/12/2015 for adjunctive treatment of seizures associated with LGS in pediatric patients aged 1 year and older.

1.2 HOW SUPPLIED

Banzel™ (rufinamide) is available in dosage forms as follows¹:

- NDA#21911 approved on 11/14/2008: oral film coated tablet (200 mg and 400 mg)
- NDA#201367 approved on 3/3/2011: oral suspension (460 mL bottles, 40 mg/ml)

2 METHODS AND MATERIALS

We used proprietary drug utilization databases available to FDA to conduct this analysis. Appendix A provides full database descriptions.

2.1 DATA SOURCES USED

QuintilesIMS, National Sales Perspectives™ (NSP) database was used to determine the settings of care where Banzel (rufinamide) was distributed from the manufacturers to various U.S. distribution channels in 2016.

QuintilesIMS, Total Patient Tracker™ (TPT) database was used to obtain the nationally estimated number of patients who received a dispensed prescription for Banzel (rufinamide) tablets or suspension from U.S. outpatient retail pharmacies, stratified by patient age (< 1-year-old, 1-4, 5-11, 12-16, and 17 years and older), February 1, 2015 through May 31, 2017, aggregated.

¹ Banzel [package insert]. Distributed by Eisai Inc., Woodcliff Lake, NJ 07677; Revised June 2015

3 RESULTS

3.1 SETTINGS OF CARE

According to sales distribution data for 2016, 75% of Banzel (rufinamide) tablet and suspension in bottles were sold to U.S. outpatient retail pharmacies, followed by 21% to non-retail (primarily long-term care), and 3% to mail-order/specialty pharmacy settings of care ². Accordingly, we focused our review on the U.S. outpatient retail pharmacy setting of care; data from mail-order/specialty pharmacies and non-retail settings were not included in this review.

3.2 U.S. OUTPATIENT RETAIL PHARMACY PATIENT DATA

Table 3.2 below provides the nationally estimated number of patients who received a prescription for Banzel (rufinamide) tablet or suspension from U.S. outpatient retail pharmacies, stratified by patient age (< 1 year, 1-4, 5-11, 12-16, 17 years and older), February 1, 2015 through May 31, 2017, aggregated.

Pediatric patients aged 0-16 years comprised 58% (approximately 7,700 patients) of the total patients during the examined time period. Among pediatric patients, those aged 5-11 years comprised the greatest proportion at 55% (approximately 4,200 patients), followed by those aged 12-16 years at 42% (approximately 3,300 patients) and those aged 1-4 years with 17% (approximately 1,300 patients). Pediatric patients younger than 1 year old accounted for less than 1% (approximately 30 patients).

Table 1. Nationally estimated number of patients with a dispensed prescription for Banzel (rufinamide), stratified by patient age, from U.S. outpatient retail pharmacies, February 1, 2015 - May 31, 2017, aggregated

	Feb 2015 - May 2017	
	Patients (N)	Share %
Total Patients	13,353	100.0%
Age 0 - 16 years	7,714	57.8%
< 1 yr	32	0.4%
1 - 4 yrs	1,312	17.0%
5 - 11 yrs	4,229	54.8%
12 - 16 yrs	3,266	42.3%
Age 17 years and older	6,680	50.0%
Age Unknown	71	0.5%

Source: QuintilesIMS, Total Patient Tracker™. Feb 2015 - May 2017. Extracted Aug 2017. File: TPT 2017-1002 rufinamide BPCA Aug 2017.xlsx

Note: Subtotals may not sum exactly because of patients aging during the study period. Patients can be counted more than once in the individual age categories. Therefore, summing across patient age bands is not advisable and will result in overestimates of patient counts.

*Includes Banzel (rufinamide) oral tablets and oral suspension formulation.

² IMS Health, National Sales Perspective; Extracted Aug-12-2017.

4 DISCUSSION

Drug utilization findings should be interpreted in context of the known limitations of the databases used. The patient estimates provided only represent the outpatient U.S. retail pharmacy setting and do not necessarily represent utilization from mail-order/specialty and non-retail pharmacy settings such as clinics or hospitals. In addition, our results could not be validated as we do not currently have access to patient medical records.

5 CONCLUSION

We observed approximately 58% of the total use of rufinamide was in pediatric patients aged 0-16 years. Use in pediatric patients younger than 1 year old was negligible.

6 APPENDIX A. DRUG USE DATABASE DESCRIPTIONS

QuintilesIMS, National Sales Perspectives™: Retail and Non-Retail

The QuintilesIMS, IMS National Sales Perspectives™ measures the volume of drug products, both prescription and over-the-counter, and selected diagnostic products moving from manufacturers into various outlets within the retail and non-retail markets. Volume is expressed in terms of sales dollars, eaches, extended units, and share of market. These data are based on national projections. Outlets within the retail market include the following pharmacy settings: chain drug stores, independent drug stores, mass merchandisers, food stores, and mail service. Outlets within the non-retail market include clinics, non-federal hospitals, federal facilities, HMOs, long-term care facilities, home health care, and other miscellaneous settings.

QuintilesIMS, Total Patient Tracker (TPT)

Total Patient Tracker (TPT) is a national-level projected audit designed to estimate the total number of unique patients across all drugs and therapeutic classes in the retail outpatient setting over time. TPT derives its data from the VectorOne® database which integrates prescription activity from a sample received from payers, switches, and other software systems that may arbitrage prescriptions at various points in the sales cycle. VectorOne® receives over 2.1 billion prescription claims per year.

Unique patient counts may not be added across time periods due to the possibility of double counting those patients who are receiving treatment over multiple periods in the study. Furthermore, patient age subtotals may not sum exactly due to patients aging during the study period, and may be counted more than once in the individual age categories. For this reason, summing across time periods or patient age bands is not advisable and will result in overestimates of patient counts.

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/s/

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11/17/2017

Banzel Drug Utilization review authored by Joann Lee. This review is an addendum to the DPV
Banzel pediatric FAERS review authored by Charlene Flowers

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