Department of Health and Human Services
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Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Pharmacovigilance and Epidemiology

Pediatric Postmarketing Pharmacovigilance Review

Date:	November 7, 2025
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Product Name:	Suprep Bowel Prep Kit (sodium sulfate, potassium sulfate, and magnesium sulfate) oral solution
Pediatric Labeling Approval Date:	August 5, 2020
Application Type/Number:	NDA 022372
Applicant:	Braintree Laboratories, Inc.
TTT Record ID:	2025-16262

TABLE OF CONTENTS

EXECUTIVE SUMMARY

This review evaluates FDA Adverse Event Reporting System (FAERS) reports for Suprep Bowel Prep Kit (sodium sulfate, potassium sulfate, and magnesium sulfate) oral solution in pediatric patients less than 17 years of age. The Division of Pharmacovigilance (DPV) conducted this review in accordance with the Pediatric Research Equity Act (PREA). This review focuses on United States (U.S.) serious unlabeled adverse events associated with sodium sulfate\potassium sulfate\magnesium sulfate oral solution in pediatric patients.

Suprep Bowel Prep Kit (sodium sulfate, potassium sulfate, and magnesium sulfate) oral solution is an osmotic laxative indicated for cleansing of the colon in preparation for colonoscopy. It was first approved on August 5, 2010, for use in adult patients. On August 5, 2020, FDA expanded the indication for Suprep Bowel Prep Kit to include use in pediatric patients 12 years of age and older.

This pediatric postmarketing safety review was prompted by the pediatric labeling on August 5, 2020.

DPV has not previously performed a pediatric postmarketing pharmacovigilance review of sodium sulfate\potassium sulfate\magnesium sulfate oral solution for the Pediatric Advisory Committee.

DPV reviewed all U.S. serious FAERS reports with sodium sulfate\potassium sulfate\magnesium sulfate oral solution in pediatric patients less than 17 years of age from August 5, 2010, through August 31, 2025, and identified one report; however, the report was excluded from further discussion.

There were no new safety signals identified, no increased severity of any labeled adverse events, and no deaths directly associated with sodium sulfate\potassium sulfate\magnesium sulfate oral solution in pediatric patients less than 17 years of age.

DPV did not identify any new pediatric safety concerns for sodium sulfate\potassium sulfate\magnesium sulfate oral solution\ at this time and will continue routine pharmacovigilance monitoring for sodium sulfate\potassium sulfate\magnesium sulfate oral solution.

1 INTRODUCTION

This review evaluates FDA Adverse Event Reporting System (FAERS) reports for Suprep Bowel Prep Kit (sodium sulfate, potassium sulfate, and magnesium sulfate) oral solution in pediatric patients less than 17 years of age. The Division of Pharmacovigilance (DPV) conducted this review in accordance with the Pediatric Research Equity Act (PREA). This review focuses on United States (U.S.) serious unlabeled adverse events associated with sodium sulfate\potassium sulfate\magnesium sulfate oral solution in pediatric patients.

1.1 PEDIATRIC REGULATORY HISTORY

Suprep Bowel Prep Kit (sodium sulfate, potassium sulfate, and magnesium sulfate) oral solution is an osmotic laxative indicated for cleansing of the colon in preparation for colonoscopy. It was first approved on August 5, 2010, for use in adult patients.[1] On August 5, 2020, FDA expanded the indication for Suprep Bowel Prep Kit to include use in pediatric patients 12 years of age and older.[2]

This pediatric postmarketing safety review was prompted by the pediatric labeling on August 5, 2020.

DPV has not previously performed a pediatric postmarketing pharmacovigilance review of sodium sulfate\potassium sulfate\magnesium sulfate oral solution for the Pediatric Advisory Committee.

1.2 RELEVANT LABELED SAFETY INFORMATION

The Suprep Bowel Prep Kit labeling contains the following safety information excerpted from the Highlights of Prescribing Information and the *Pediatric Use* subsection. For additional Suprep Bowel Prep Kit labeling information, please refer to the full prescribing information.[2]

----------CONTRAINDICAT IONS----------

- Gastrointestinal obstruction or ileus (4, 5.6)
- Bowel perforation (4, 5.6)
- Toxic colitis or toxic megacolon (4)
- Gastric retention (4)
- Hypersensitivity to any ingredient (4)

----------WARNINGS AND PRECAUT IONS----------

- Risk of fluid and electrolyte abnormalities: Encourage adequate hydration, assess concurrent medications, and consider laboratory assessments prior to and after each use. (5.1, 7.1)
- Cardiac arrhythmias: Consider pre-dose and post-colonoscopy ECGs in patients at increased risk. (5.2)
- Seizures: Use caution in patients with a history of seizures and patients at increased risk of seizures, including medications that lower the seizure threshold. (5.3, 7.1)
- Patients with renal impairment or taking concomitant medications that affect renal function: Use caution, ensure adequate hydration and consider laboratory testing. (5.4, 7.1)
- Suspected GI obstruction or perforation: Rule out the diagnosis before administration. (4, 5.6)
- Patients at risk for aspiration: Observe during administration. (5.7)

----------ADVERSE REACT IONS----------

Most common adverse reactions are:

- Adults (>2%): overall discomfort, abdominal distention, abdominal pain, nausea, and vomiting. (6.1)
- Pediatric Patients (>10%): nausea, abdominal pain, abdominal bloating and vomiting. (6.1)

8.4 Pediatric Use

The safety and effectiveness of SUPREP Bowel Prep Kit (two 4.5-ounce doses) have been established for cleansing of the colon as a preparation for colonoscopy in pediatric patients 12 years of age and older. Use of SUPPREP Bowel Prep Kit in this age group is supported by evidence from an adequate and well-controlled trial of SUPREP Bowel Prep Kit in adults and a single, dose-ranging, controlled trial in 89 pediatric patients 12 years to 16 years of age [see Clinical Studies (14)]. In the pediatric trial, SUPREP Bowel Prep Kit (two 6-ounce doses) did not demonstrate additional treatment benefit and more patients reported gastrointestinal adverse reactions compared to SUPREP Bowel Prep Kit (two 4.5-ounce doses). Therefore, SUPREP Bowel Prep Kit (two 6-ounce doses) is not recommended for pediatric patients 12 years of age and older [see Dosage and Administration (2.3)]. The safety profile of SUPREP Bowel Prep Kit (two 4.5-ounce doses) in this pediatric population was similar to that seen in adults [see Adverse Reactions (6.1)]. The safety and effectiveness of SUPREP Bowel Prep Kit in pediatric patients less than 12 years of age have not been established.

2 METHODS AND MATERIALS

DPV searched the FAERS database with the strategy described in **Table 1**.

Table 1. FAERS Search Strategy[*]

Date of search	September 2, 2025
Time period of search	August 5, 2010[†] - August 31, 2025
Search type	RxLogix Pediatric Focused Review Alert – DPV
Product terms	Product active ingredient: Magnesium sulfate\potassium sulfate\sodium sulfate
MedDRA search terms (Version 28.0)	All Preferred Terms

[*] See Appendix A for a description of the FAERS database
[†] Suprep Bowel Prep Kit U.S. approval date.
Abbreviation: MedDRA=Medical Dictionary for Regulatory Activities

3 RESULTS

3.1 SELECTION OF U.S. SERIOUS PEDIATRIC CASES IN FAERS

Our FAERS search retrieved one U.S. serious pediatric reports for patients less than 17 years old from August 5, 2010, through August 31, 2025. We reviewed this U.S. FAERS pediatric report with a serious outcome and excluded it from further discussion as it described a labeled adverse event not representing increased severity.

3.2 SUMMARY OF U.S. FATAL PEDIATRIC CASES (N=0)

There are no fatal pediatric adverse event cases for discussion.

3.3 SUMMARY OF U.S. SERIOUS NON-FATAL PEDIATRIC CASES (N=0)

There are no non-fatal pediatric adverse event cases for discussion.

4 DISCUSSION

DPV reviewed all U.S. serious FAERS reports with sodium sulfate\potassium sulfate\magnesium sulfate in pediatric patients less than 17 years of age from August 5, 2010, to August 31, 2025, and identified one report; however, the report was excluded from further discussion.

There were no new safety signals identified, no increased severity of any labeled adverse events, and no deaths directly associated with sodium sulfate\potassium sulfate\magnesium sulfate in pediatric patients less than 17 years of age.

5 CONCLUSION

DPV did not identify any new pediatric safety concerns for sodium sulfate\potassium sulfate\magnesium sulfate at this time and will continue routine pharmacovigilance monitoring for sodium sulfate\potassium sulfate\magnesium sulfate.

6 REFERENCES

1. Suprep Bowel Prep Kit (sodium sulfate, potassium sulfate, and magnesium sulfate) oral solution. [Prescribing information]. Braintree, MA; Braintree Laboratories, Inc: August 2010.
2. Suprep Bowel Prep Kit (sodium sulfate, potassium sulfate, and magnesium sulfate) oral solution. [Prescribing information]. Braintree, MA; Braintree Laboratories, Inc: July 2020.

7 APPENDICES

7.1 APPENDIX A. FDA ADVERSE EVENT REPORTING SYSTEM (FAERS)

The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support FDA's postmarketing safety surveillance program for drug and therapeutic biological products. The informatic structure of the database adheres to the international safety reporting guidance issued by the International Council on Harmonisation. Adverse events and medication errors are coded to terms in the Medical Dictionary for Regulatory Activities terminology. The suspect products are coded to valid tradenames or active ingredients in the FAERS Product Dictionary.

FAERS data have limitations. First, there is no certainty that the reported event was actually due to the product. FDA does not require that a causal relationship between a product and event be proven, and reports do not always contain enough detail to properly evaluate an event. Further, FDA does not receive reports for every adverse event or medication error that occurs with a product. Many factors can influence whether an event will be reported, such as the time a product has been marketed and publicity about an event. Therefore, FAERS data cannot be used to calculate the incidence of an adverse event or medication error in the U.S. population.