

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

022372Orig1s000

REMS

NDA 22-372 SUPREP® Bowel Prep Kit (sodium sulfate, potassium sulfate and magnesium sulfate) Oral Solution

Gastrointestinal Lavage

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RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I GOAL(S)

The goal of the REMS for SUPREP Bowel Prep Kit (sodium sulfate, potassium sulfate and magnesium sulfate) Oral Solution is to communicate the risks of serious fluid and serum chemistry abnormalities associated with osmotic bowel preparations to patients.

II REMS ELEMENTS

A Medication Guide

A Medication Guide will be dispensed with each SUPREP Bowel Prep Kit in accordance with 21 CFR 208.24. Product and carton labels will prominently state that the Medication Guide enclosed in the kit should be dispensed to each patient.

B Timetable for Submission of Assessments

Braintree Laboratories will submit REMS Assessments to FDA 18 months, 3 years and 7 years from the date of approval of the REMS. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for the assessment. Braintree will submit each assessment so that it will be received by the FDA on or before the due date.

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