

FIRST TIME GENERIC APPROVAL

Brand Name	Suprep® Bowel Prep Kit
Generic Name	sodium sulfate, potassium sulfate, magnesium sulfate
Drug Manufacturer	Affordable Pharmaceuticals, LLC

New Drug Approval

TYPE OF CLINICAL UPDATE

First time generic

FDA APPROVAL DATE

July 1, 2020

LAUNCH DATE

July 8, 2022

REVIEW DESIGNATION

N/A

TYPE OF REVIEW

ANDA 202511

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

sodium sulfate, potassium sulfate and magnesium sulfate oral solution is an osmotic laxative indicated for cleansing of the colon in preparation for colonoscopy in adult and pediatric patients 12 years of age and older.

MECHANISMS OF ACTION

Sulfate salts provide sulfate anions, which are poorly absorbed. The osmotic effect of unabsorbed sulfate anions and the associated cations causes water to be retained within the gastrointestinal tract.

DOSE FORM AND STRENGTH

- Sodium sulfate, potassium sulfate and magnesium sulfate oral solution (for adults): Two bottles each containing 6 ounces of an oral solution of 17.5 grams sodium sulfate, 3.13 grams potassium sulfate, and 1.6 grams magnesium sulfate.
- Sodium sulfate, potassium sulfate and magnesium sulfate oral solution (for pediatric patients 12 years of age and older): Two bottles each containing 4.5-ounces of an oral solution of 13.13 grams sodium sulfate, 2.35 grams potassium sulfate, and 1.2 grams magnesium sulfate.

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DOSE & ADMINISTRATION

- Split-Dose (two-day) regimen consists of two doses of sodium sulfate, potassium sulfate and magnesium sulfate Oral Solution: first dose during the evening prior to colonoscopy and second dose the next day, during the morning of colonoscopy.
- Recommended sodium sulfate, potassium sulfate and magnesium sulfate oral solution dosage is:
 - Adults: Two 6-ounce doses.
 - Pediatric Patients 12 Years of Age and Older: Two 4.5-ounce doses.

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