

## NEW DRUG APPROVAL

<b>Brand Name</b>	Sutab®
<b>Generic Name</b>	magnesium sulfate, sodium sulfate, potassium chloride
<b>Drug Manufacturer</b>	Braintree Labs

### New Drug Approval

FDA Approval Date: November 10, 2020

Review Designation: Standard; Orphan

Type of Review: Type 3 - New Dosage Form; New Drug Application (NDA): 213135

Dispensing Restrictions: Open

### Place in Therapy

#### DISEASE DESCRIPTION & EPIDEMIOLOGY

Colonoscopy is the most common detection method for colorectal cancer, a leading cause of cancer-related deaths that can be managed more effectively through screening. It is considered the gold standard of colorectal cancer screening methods for its ability to view the entire colon and both detect and remove polyps during the same procedure. Nineteen million colonoscopies are performed in the U.S. every year. For those patients, particularly those who have had difficulty completing colonoscopy preparation in the past, Sutab® presents a welcome alternative to liquid bowel preparation.

### Efficacy

In two pivotal trials, 92% of patients achieved successful bowel cleansing with Sutab® and 92%-95% of patients achieved successful cleansing in all segments of the colon, including the proximal colon. In one pivotal trial, 91% of patients rated Sutab® as very easy to tolerable to consume. Seventy-eight percent said they would request Sutab® again for a future colonoscopy. Fifty-two percent of all Sutab® and MoviPrep® patients reported at least one selected gastrointestinal adverse reaction. More Sutab® patients reported experiencing nausea and vomiting than the comparator, with ≤1% of these reports considered severe.

The primary efficacy endpoint in each trial was the proportion of patients with successful colon cleansing, as assessed by the blinded colonoscopist utilizing the four-point scaled described below. Success was defined as an overall cleansing assessment of 3 (Good) or 4 (Excellent).

Score	Grade	Description
1	Poor	Large amount of fecal residue, additional bowel preparation required.
2	Fair	Enough feces even after washing and suctioning to prevent clear visualization of the entire colonic mucosa.
3	Good	Feces and fluid requiring washing and suctioning, but still achieves clear visualization of the entire colonic mucosa.
4	Excellent	No more than small bits of feces/fluid which can be suctioned easily; achieves clear visualization of the entire colonic mucosa.

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	SUTAB % (n/N)	Comparator % (n/N)	SUTAB-comparator	
			Difference <sup>b</sup> (%)	99% Confidence Interval <sup>b</sup>
Study 1	92% (257/278)	89% <sup>c</sup> (241/270)	3.0	(-3.2, 9.3) <sup>e</sup>
Study 2	92% (175/190)	88% <sup>d</sup> (174/198)	3.1	(-4.5, 10.7) <sup>e</sup>

<sup>a</sup> Success was defined as an overall cleaning assessment of 3 (Good) or 4 (Excellent) by the blinded endoscopist, scores were assigned on withdrawal of colonoscope.

<sup>b</sup> treatment differences and confidence intervals were adjusted by study sites based on Mantel-Haenszel method

<sup>c</sup> comparator in Study 1 was polyethylene glycol 3350, sodium sulfate, sodium chloride, potassium chloride, sodium ascorbate and ascorbic acid for oral solution

<sup>d</sup> comparator in Study 2 was sodium picosulfate, magnesium oxide, and anhydrous citric acid for oral solution

<sup>e</sup> non-inferior

## Safety

### ADVERSE EVENTS

Most common gastrointestinal adverse reactions are nausea, abdominal distension, vomiting and upper abdominal pain.

### WARNINGS & PRECAUTIONS

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

### CONTRAINDICATIONS

Sutab® is contraindicated in the following conditions:

- Gastrointestinal obstruction or ileus
- Bowel perforation
- Toxic colitis or toxic megacolon
- Gastric retention

## Clinical Pharmacology

### MECHANISMS OF ACTION

The primary mode of action is osmotic action of sodium sulfate and magnesium sulfate, which induce a laxative effect. The physiological consequence is increased water retention in the lumen of the colon, resulting in loose stools.

## Dose & Administration

### ADULTS

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The recommended Split-Dose regimen for adults consists of two doses of Sutab® (Dose 1 & Dose 2).

**Evening before the colonoscopy (Dose 1):** 12 tablets PO along with 16 oz of water (use provided container to measure), ingested over 15 to 20 minutes. Approximately 1 hour after the last tablet is ingested, the patient must drink another 16 oz of water over 30 minutes. Approximately 30 minutes after finishing the second container of water, the patient must drink another 16 oz of water over 30 minutes.

**On the day of colonoscopy (5 to 8 hours before the procedure and no sooner than 4 hours from starting Dose 1):** 12 tablets PO along with 16 oz of water, ingested over 15 to 20 minutes. Repeat the same process as the day before for subsequent water intake.

### PEDIATRICS

N/A

### GERIATRICS

Refer to adult dosing

### RENAL IMPAIRMENT

N/A

### HEPATIC IMPAIRMENT

N/A

## Product Availability

### DOSAGE FORM(S) & STRENGTH(S)

Tablets: 1.479 g sodium sulfate, 0.225 g magnesium sulfate, and 0.188 g potassium chloride.