

# THE TABLET CHOICE IN BOWEL PREPARATION

## SUTAB® (sodium sulfate, magnesium sulfate, and potassium chloride) Tablets 1.479 g/0.225 g/0.188 g



### IMPORTANT SAFETY INFORMATION

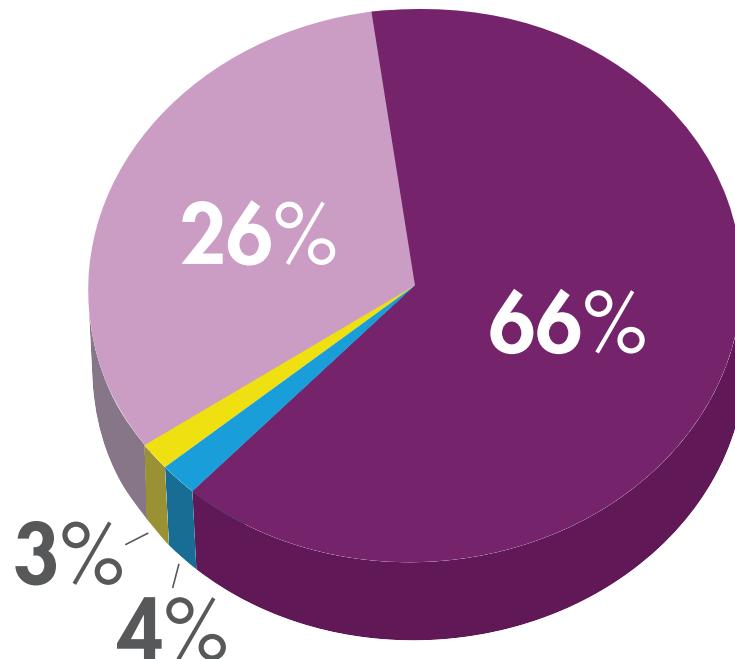
SUTAB® (sodium sulfate, magnesium sulfate, potassium chloride) tablets for oral use is an osmotic laxative indicated for cleansing of the colon in preparation for colonoscopy in adults.

**DOSAGE AND ADMINISTRATION:** A low residue breakfast may be consumed. After breakfast, only clear liquids may be consumed until after the colonoscopy. Administration of two doses of SUTAB (24 tablets) are required for a complete preparation for colonoscopy. Twelve (12) tablets are equivalent to one dose. Each SUTAB bottle contains a desiccant. **Remove and discard the desiccant** from both bottles the evening prior to the colonoscopy. Water must be consumed with each dose of SUTAB and additional water must be consumed after each dose. Complete all SUTAB tablets and required water at least 2 hours before colonoscopy.

**CONTRAINDICATIONS:** Use is contraindicated in the following conditions: gastrointestinal obstruction or ileus, bowel perforation, toxic colitis or toxic megacolon, gastric retention, hypersensitivity to any ingredient in SUTAB.

*Please see page 14 for additional Important Safety Information, and accompanying Full Prescribing Information and Medication Guide.*

**92% OF PATIENTS IN TWO PIVOTAL TRIALS  
 ACHIEVED SUCCESSFUL BOWEL CLEANSING WITH SUTAB<sup>1,2\*</sup>**



*A prep is considered successful if it is good or excellent<sup>1,2\*</sup>*

- 97% agreement was seen between central and local readers<sup>1</sup>

**SUTAB Split-Dose Regimen<sup>†</sup>**

■ Excellent   ■ Good   ■ Fair   ■ Poor

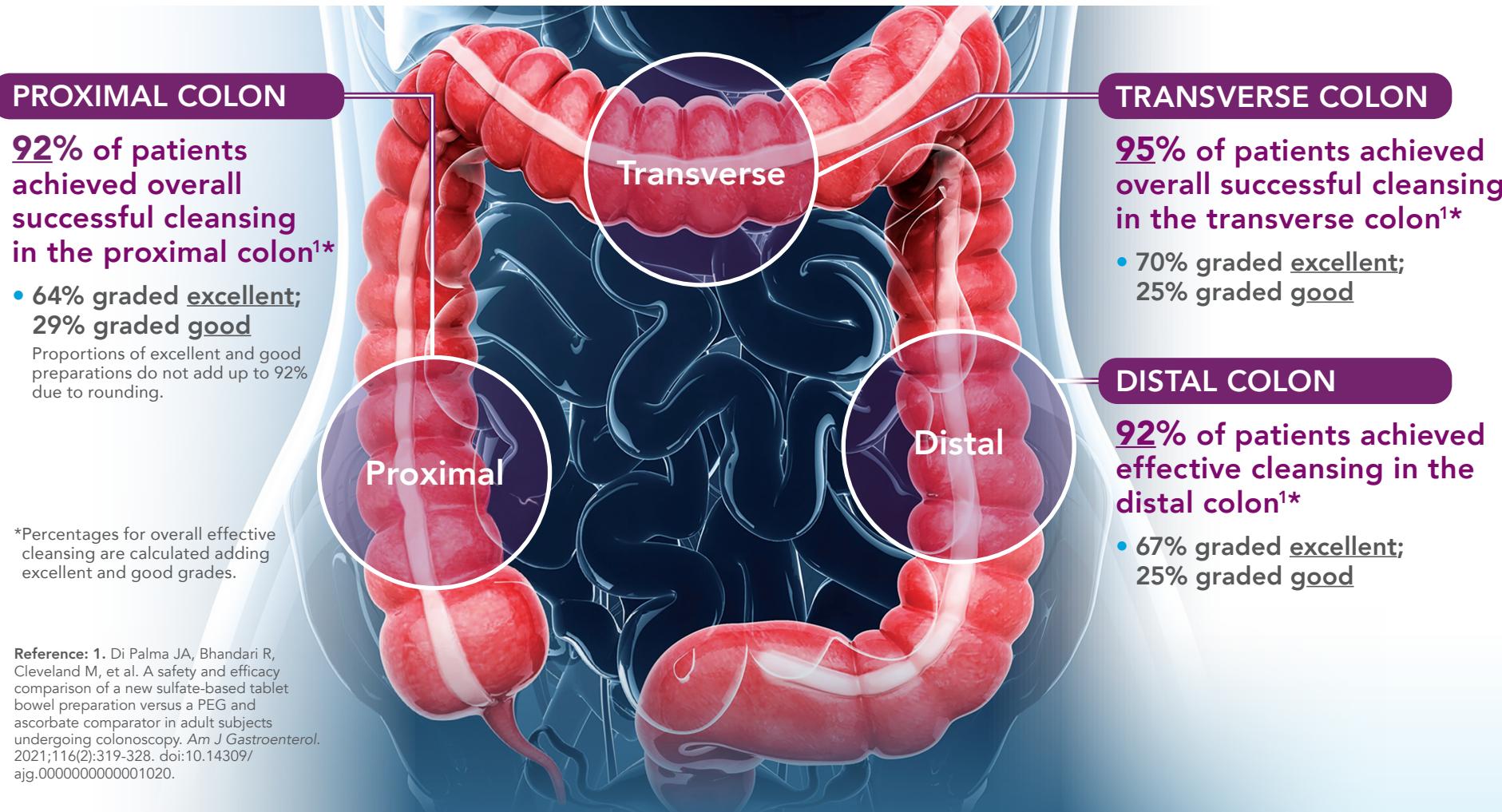
**Study Design<sup>1</sup>:** Study 1 was a phase 3 trial that was conducted in 22 US sites. Of the 620 subjects who enrolled, 548 patients were evaluable for efficacy analyses. The primary endpoint was the percentage of subjects with successful cleansing, which was based on the US FDA Bowel Prep Scoring Scale, the goal of which was to determine non-inferiority against MoviPrep®. Safety follow-up visits were required 24-48 hours after colonoscopy and on days 7 and 30 if adverse events or lab abnormalities were indicated. A subset of colonoscopies was graded by central readers (exploratory). The primary endpoint of non-inferiority was met.

\*Success was the primary endpoint and was defined in non-inferiority trials as an overall cleansing assessment of 3 (good) or 4 (excellent) by the blinded endoscopist; scores were assigned following completion of the colonoscopy.

<sup>†</sup>Two patients (0.7%) were unable to complete their preparation and are included as missing.

MoviPrep is a registered trademark of Velinor AG.

**92%–95% OF PATIENTS IN ONE PIVOTAL TRIAL ACHIEVED SUCCESSFUL CLEANSING IN ALL SEGMENTS OF THE COLON, INCLUDING THE PROXIMAL COLON<sup>1</sup>**



## 4 SUTAB EFFICACY: HARD-TO-PREP POPULATION

**90%–96% OF HARD-TO-PREP PATIENTS  
IN ONE PIVOTAL TRIAL ACHIEVED SUCCESSFUL CLEANSING<sup>1\*</sup>**

**SUTAB<sup>®</sup>**  
(sodium sulfate, magnesium sulfate, and potassium chloride)  
Tablets  
1.479 g/0.225 g/0.188 g

Subgroup of Patients (n=164)		
Hard-to-Prep Patients (n=115)	Successful Cleansing Rate	Excellent Cleansing Rate
History of constipation		
Opioid use	90%	61%
Failed colonoscopy		
BMI $\geq 35$		
Afternoon colonoscopy (n=49)	96%	74%

- A subgroup of patients with known predictors of suboptimal preparation were analyzed
- Hard-to-prep patients included those with history of constipation, current opioid users, BMI  $\geq 35$ , those who failed previous preparation; and those who had a planned afternoon colonoscopy
- SUTAB achieved high rates of success in both subgroups

BMI=body mass index

\*Success was defined as cleansing graded either excellent or good.

**Reference:** 1. Di Palma JA, Bhandari R, Cleveland M, et al. A safety and efficacy comparison of a new sulfate-based tablet bowel preparation versus a PEG and ascorbate comparator in adult subjects undergoing colonoscopy. *Am J Gastroenterol.* 2021;116(2):319-328. doi:10.14309/ajg.0000000000001020.

## 5 SUTAB EFFICACY: SECONDARY ENDPOINTS



**>98% OF EXAMS REACHED THE CECUM**

**IN ONE PIVOTAL TRIAL, WITH 97% DEEMED ADEQUATE BY ENDOSCOPISTS<sup>1</sup>**

Secondary Endpoints <sup>1</sup>	
Endpoint	SUTAB Result
Cecal intubation rate	98%
Preparation adequacy	97%
Procedure duration (median)	13.5 minutes
Intraprocedural water volume (median)	30 mL

- Adenoma detection success rate was 33% in patients taking SUTAB (n=278)<sup>1</sup>
- ASGE/ACG Task Force on Quality Indicators targets  $\geq 85\%$  adequate bowel preps to allow the use of recommended surveillance or screening intervals<sup>3</sup>

ACG=American College of Gastroenterology

ASGE=American Society for Gastrointestinal Endoscopy

**References:** 1. Di Palma JA, Bhandari R, Cleveland M, et al. A safety and efficacy comparison of a new sulfate-based tablet bowel preparation versus a PEG and ascorbate comparator in adult subjects undergoing colonoscopy. *Am J Gastroenterol.* 2021;116(2):319-328. doi:10.14309/ajg.0000000000001020. 3. Rex DK, Schoenfeld PS, Cohen J, et al. Quality indicators for colonoscopy. *Gastrointest Endosc.* 2015;81(1):31-53.

## 6 SUTAB TOLERABILITY: GENERAL AND ELDERLY POPULATIONS

**SUTAB®**  
(sodium sulfate, magnesium sulfate, and potassium chloride)  
Tablets  
1.479 g/0.225 g/0.188 g

**91% OF PATIENTS IN ONE PIVOTAL TRIAL  
RATED SUTAB AS TOLERABLE TO VERY EASY TO CONSUME<sup>1\*</sup>**

### Patient Preference Data<sup>1</sup>

<i>How was your overall experience?</i>	<b>72%</b> said it was <b>good or excellent</b>
<i>How easy was it to take SUTAB?</i>	<b>65%</b> said it was <b>easy to very easy</b>
<i>How did SUTAB compare with other preps you've taken?</i>	<b>65%</b> said it was <b>better</b>

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 competitor, with  $\leq 1\%$  of these reports considered severe.<sup>2†</sup> Four percent of SUTAB patients reported they had a bad preparation experience, 3% reported that the prep was very difficult to consume, and 15% said it was worse than their prior bowel prep experience.<sup>1</sup>

*Would you request  
SUTAB again?*



*of patients in one pivotal trial would  
request it for a future colonoscopy<sup>1\*</sup>*

\*Patients completed a preference questionnaire following completion of study drug to capture their perceptions of the preparation experience. This questionnaire has not undergone formal validation.

†Patients were queried for selected gastrointestinal adverse reactions of upper abdominal pain, abdominal distension, nausea, and vomiting following completion of study drug, rating the intensity as mild, moderate, or severe.<sup>1,2</sup>

IN ALL GROUPS, MOST SYMPTOMS WERE MILD<sup>1,2</sup>

## Study 1: SUTAB and MoviPrep® GI Symptoms by Severity

Solicited Symptoms*	SUTAB (N=281)		MoviPrep (N=271)	
% Nausea	48%		26%	
Mild	% Overall <sup>†</sup>	% by Symptom <sup>‡</sup>	% Overall <sup>†</sup>	% by Symptom <sup>‡</sup>
	35	71	20	77
	13	27	6	23
Severe	1	2	0	0
% Abdominal distension	29%		22%	
Mild	% Overall <sup>†</sup>	% by Symptom <sup>‡</sup>	% Overall <sup>†</sup>	% by Symptom <sup>‡</sup>
	21	68	16	71
	9	30	6	29
Severe	0	1	0	0
% Vomiting	23%		5%	
Mild	% Overall <sup>†</sup>	% by Symptom <sup>‡</sup>	% Overall <sup>†</sup>	% by Symptom <sup>‡</sup>
	11	48	3	46
	12	52	3	54
Severe	0	0	0	0
% Upper abdominal pain	16%		18%	
Mild	% Overall <sup>†</sup>	% by Symptom <sup>‡</sup>	% Overall <sup>†</sup>	% by Symptom <sup>‡</sup>
	11	65	13	71
	6	35	6	29
Severe	0	0	0	0

\*During Studies 1 and 2, patients were queried for selected GI adverse reactions using a standard questionnaire, following completion of study prep.

<sup>†</sup>Proportion of subjects reporting a specific symptom/severity out of all subjects who took that prep (N).<sup>1</sup>

<sup>‡</sup>Proportion of subjects reporting a specific severity out of those that reported that specific symptom.<sup>2</sup>

MoviPrep is a registered trademark of Velinor AG.

Symptom definitions<sup>1,2</sup>

**Mild/barely noticeable:** Does not influence functioning, causing no limitations of usual activities

**Moderate:** Makes participant uncomfortable, influences functioning, causing some limitations of usual activities

**Severe:** Severe discomfort, treatment needed, severe and undesirable, causing inability to carry out usual activities

- SUTAB scored lower (worse) than the comparator in the symptom-rating categories for nausea, and vomiting<sup>1,2</sup>
- Of the 471 patients who received SUTAB in pivotal clinical trials<sup>2</sup>:
  - 32% (n=150) were 65 years of age or older
  - 5% (n=25) were 75 years of age or older
- No differences in safety or effectiveness of SUTAB were observed between geriatric and younger patients<sup>2</sup>

## 8 SUTAB TOLERABILITY: GENERAL AND ELDERLY POPULATIONS

IN ALL GROUPS, MOST SYMPTOMS WERE MILD<sup>1,2</sup>

Study 2: SUTAB and Prepopik® GI Symptoms by Severity			
Solicited Symptoms*	SUTAB (N=190)		Prepopik (N=199)
% Nausea		52%	
Mild	% Overall <sup>†</sup>	% by Symptom <sup>‡</sup>	% Overall <sup>†</sup>
39	74	17	94
Moderate	11	20	1
Severe	3	6	0
% Abdominal distension		34%	
Mild	% Overall <sup>†</sup>	% by Symptom <sup>‡</sup>	% Overall <sup>†</sup>
25	73	11	69
Moderate	9	27	5
Severe	0	0	0
% Vomiting		16%	
Mild	% Overall <sup>†</sup>	% by Symptom <sup>‡</sup>	% Overall <sup>†</sup>
9	53	1	33
Moderate	8	47	1
Severe	0	0	0
% Upper abdominal pain		23%	
Mild	% Overall <sup>†</sup>	% by Symptom <sup>‡</sup>	% Overall <sup>†</sup>
18	82	13	100
Moderate	4	16	1
Severe	1	2	0

\*During Studies 1 and 2, patients were queried for selected GI adverse reactions using a standard questionnaire, following completion of study prep.

<sup>†</sup>Proportion of subjects reporting a specific symptom/severity out of all subjects who took that prep (N).<sup>1</sup>

<sup>‡</sup>Proportion of subjects reporting a specific severity out of those that reported that specific symptom.<sup>2</sup>

Prepopik is a registered trademark of Ferring B.V.

Symptom definitions<sup>1,2</sup>

**Mild/barely noticeable:** Does not influence functioning, causing no limitations of usual activities

**Moderate:** Makes participant uncomfortable, influences functioning, causing some limitations of usual activities

**Severe:** Severe discomfort, treatment needed, severe and undesirable, causing inability to carry out usual activities

- SUTAB scored lower (worse) than the comparator in the symptom-rating categories for nausea, abdominal distention, vomiting, and upper abdominal pain<sup>1,2</sup>
- Of the 471 patients who received SUTAB in pivotal clinical trials<sup>2</sup>:
  - 32% (n=150) were 65 years of age or older
  - 5% (n=25) were 75 years of age or older
- No differences in safety or effectiveness of SUTAB were observed between geriatric and younger patients<sup>2</sup>

**98%** OF SUTAB PATIENTS IN TWO PIVOTAL  
TRIALS **WERE ABLE TO COMPLETE BOTH DOSES**  
**OF PREPARATION<sup>1,2</sup>**



**References:** 1. Di Palma JA, Bhandari R, Cleveland M, et al. A safety and efficacy comparison of a new sulfate-based tablet bowel preparation versus a PEG and ascorbate comparator in adult subjects undergoing colonoscopy. *Am J Gastroenterol.* 2021;116(2):319-328. doi:10.14309/ajg.0000000000001020. 2. SUTAB [package insert]. Braintree, MA: Braintree Laboratories, Inc.



## KEY SAFETY PARAMETERS



### ELECTROLYTES

Shifts from normal at baseline to abnormal at colonoscopy >3%?<sup>4</sup>

Changes to magnesium and serum osmolality were transient and not clinically significant



### RENAL RISK FACTORS

Acute phosphate nephropathy?<sup>2</sup>



Black Box Warning for acute phosphate nephropathy?<sup>2</sup>

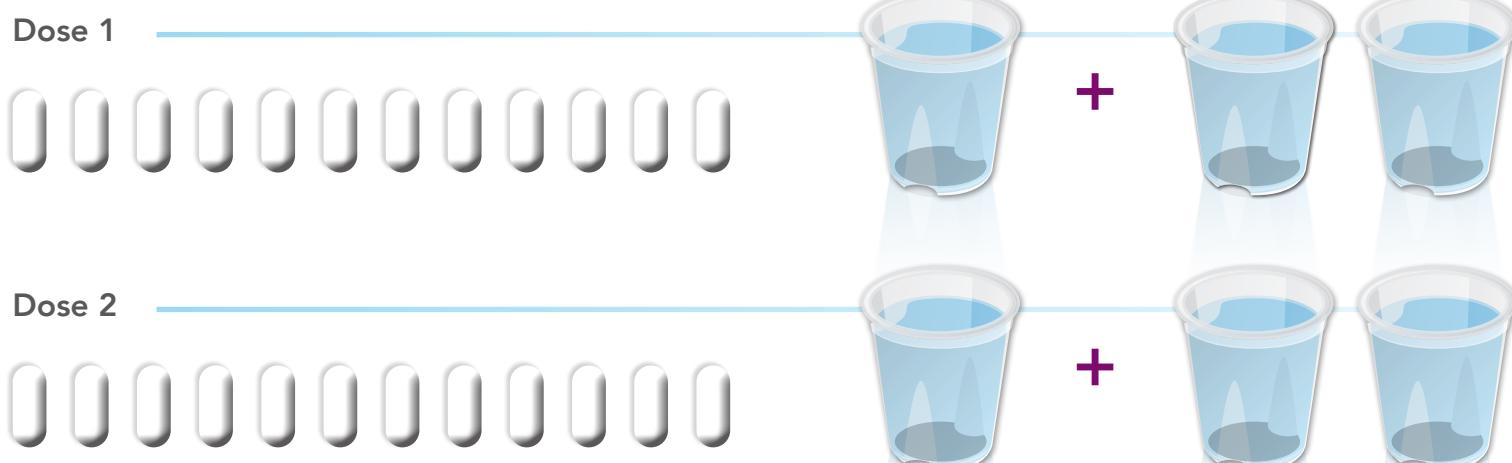


### Advise all patients to hydrate adequately before, during, and after the use of SUTAB.

If a patient develops significant vomiting or signs of dehydration after taking SUTAB, consider performing postcolonoscopy lab tests (electrolytes, creatinine, and BUN). Fluid and electrolyte disturbances can lead to serious adverse events including cardiac arrhythmias, seizures, and renal impairment. Correct fluid and electrolyte abnormalities before treatment with SUTAB. Use SUTAB with caution in patients with conditions, or who are using medications, that increase the risk for fluid and electrolyte disturbances or may increase the risk of adverse events of seizure, arrhythmias, and renal impairment.

## SUTAB SPLIT-DOSE REGIMEN

- Two SUTAB doses are required for a complete preparation<sup>2</sup>:
  - **Dose 1** consists of 12 tablets and 16 oz of water
  - **Dose 2** consists of 12 tablets and 16 oz of water
  - Each dose is followed by two additional 16 oz of water
- ACG-recommended split-dose regimen<sup>5</sup>



Tablets not shown actual size.

*Please see accompanying Full Prescribing Information and Medication Guide.*

**References:** 2. SUTAB [package insert]. Braintree, MA: Braintree Laboratories, Inc. 5. Rex DK, Johnson DA, Anderson JC, et al; American College of Gastroenterology. American College of Gastroenterology guidelines for colorectal cancer screening 2009 [corrected]. *Am J Gastroenterol.* 2009;104(3):739-750.

# HOW MUCH DOES THE PATIENT CONSUME?



## SUTAB® (split-dose regimen)<sup>2</sup>

Two SUTAB doses are required for a complete preparation:

- Dose 1 consists of 12 tablets and 16 oz of water
- Dose 2 consists of 12 tablets and 16 oz of water
- Each dose is followed by two additional 16 oz of water



## SUFLAVE™ (split-dose regimen)<sup>6</sup>

Two SUFLAVE doses are required for a complete preparation:

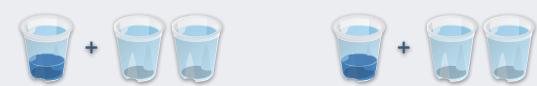
- Dose 1 consists of 1 bottle and 1 flavor-enhancing packet
- Dose 2 consists of 1 bottle and 1 flavor-enhancing packet
- Each dose is followed by an additional 16 oz of water



## SUPREP®\* (split-dose regimen)<sup>7</sup>

Two SUPREP doses are required for a complete preparation:

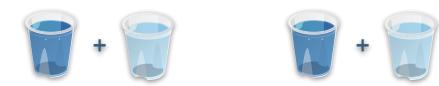
- Each dose consists of 6 oz of SUPREP liquid mixed with 10 oz of water
- Each dose is followed by two additional 16 oz of water



## Plenvu®† (split-dose regimen)<sup>8</sup>

Two Plenvu doses are required for a complete preparation:

- Dose 1 consists of approximately 16 oz of Plenvu solution (112-g packet mixed with water)
- Dose 2 consists of approximately 16 oz of Plenvu solution (100-g packet mixed with water)
- Each dose is followed by at least 16 oz of clear liquid



## Clenpiq®‡ (split-dose regimen)<sup>9</sup>

Two Clenpiq doses are required for a complete preparation:

- Dose 1 consists of one 5.4-oz bottle of Clenpiq solution followed by five or more 8-oz cups of clear liquid consumed within a 5-hour period and before bedtime
- Dose 2 consists of one 5.4-oz bottle of Clenpiq solution followed by four or more 8-oz cups of clear liquid, to be finished 2 hours before the colonoscopy



## Standard 4-Liter Prep<sup>§</sup> (day-before regimen)<sup>10</sup>

Single dose consists of approximately 135 oz of solution (divided into approximately seventeen 8-oz servings) consumed within a 4-hour period



## MiraLAX®|| + Gatorade®¶ (split-dose regimen)<sup>11</sup>

Two doses are required for a complete preparation:

- Dose 1 consists of 2 Dulcolax®# tablets followed by 33.8 oz of Gatorade mixed with 119 g of MiraLAX
- Dose 2 consists of 33.8 oz of Gatorade mixed with 119 g of MiraLAX



Tablets, bottles, and packaging not shown actual size.

\*SUFLAVE, SUTAB, and SUPREP are trademarks of Braintree Laboratories, Inc. †PLENVU is a registered trademark of Velinor AG. ‡Clenpiq is a trademark of Ferring B.V. §Standard 4-Liter Prep (sulfate-free PEG electrolyte lavage solution). ||MiraLAX is a registered trademark of Bayer HealthCare LLC. ¶Gatorade is a registered trademark of Stokely-Van Camp, Inc.

#Dulcolax is a registered trademark of A. Nattermann & Cie GmbH.

References: 2. SUTAB [package insert]. Braintree, MA: Braintree Laboratories, Inc. 6. SUFLAVE [package insert]. Braintree, MA: Braintree Laboratories, Inc. 7. SUPREP Bowel Prep Kit [package insert]. Braintree, MA: Braintree Laboratories, Inc. 8. Plenvu [package insert]. Bridgewater, NJ: Bausch Health LLC. 9. Clenpiq [package insert]. Parsippany, NJ: Ferring Pharmaceuticals, Inc. 10. Rex DK, Di Palma JA, Rodriguez R, et al.

A randomized clinical study comparing reduced-volume oral sulfate solution with standard 4-liter sulfate-free electrolyte lavage solution as preparation for colonoscopy. *Gastrointest Endosc*. 2010;72(2):328-336.

11. Matro R, Daskalakis C, Negoianu D, et al. Randomised clinical trial: polyethylene glycol 3350 with sports drink vs. polyethylene glycol with electrolyte solution as purgatives for colonoscopy—the incidence of hyponatraemia. *Aliment Pharmacol Ther*. 2014;40(6):610-619.



## WHAT DOES EACH KIT CONTAIN?

- 2** Bottles of 12 tablets each
- 1** 16-oz cup
- 1** Patient booklet, which includes:
  - Instructions for Use
  - Full Prescribing Information
  - Medication Guide



Tablets and packaging not shown actual size.

## 14 SUTAB IMPORTANT SAFETY INFORMATION



### IMPORTANT SAFETY INFORMATION

#### INDICATION

SUTAB® (sodium sulfate, magnesium sulfate, potassium chloride) tablets for oral use is an osmotic laxative indicated for cleansing of the colon in preparation for colonoscopy in adults.

#### DOSAGE AND ADMINISTRATION

A low residue breakfast may be consumed. After breakfast, only clear liquids may be consumed until after the colonoscopy. Administration of two doses of SUTAB (24 tablets) are required for a complete preparation for colonoscopy. Twelve (12) tablets are equivalent to one dose. Each SUTAB bottle contains a desiccant. **Remove and discard the desiccant** from both bottles the evening prior to the colonoscopy. Water must be consumed with each dose of SUTAB and additional water must be consumed after each dose. Complete all SUTAB tablets and required water at least 2 hours before colonoscopy.

#### CONTRAINDICATIONS

Use is contraindicated in the following conditions: gastrointestinal obstruction or ileus, bowel perforation, toxic colitis or toxic megacolon, gastric retention, hypersensitivity to any ingredient in SUTAB.

#### WARNINGS AND 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; Colonic mucosal ulcerations: Consider potential for mucosal ulcerations when interpreting colonoscopy findings in patients with known or suspected inflammatory bowel disease. Suspected GI obstruction or perforation: Rule out the diagnosis before administration. Hypersensitivity reactions, including anaphylaxis: Inform patients to seek immediate medical care if symptoms occur. Risk of Gastrointestinal Complications with Ingestion of Desiccant: Postmarketing reports of ingestion of the desiccant along with SUTAB tablets has been reported and may be associated with risk of gastrointestinal complications and/or choking.

#### ADVERSE REACTIONS

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

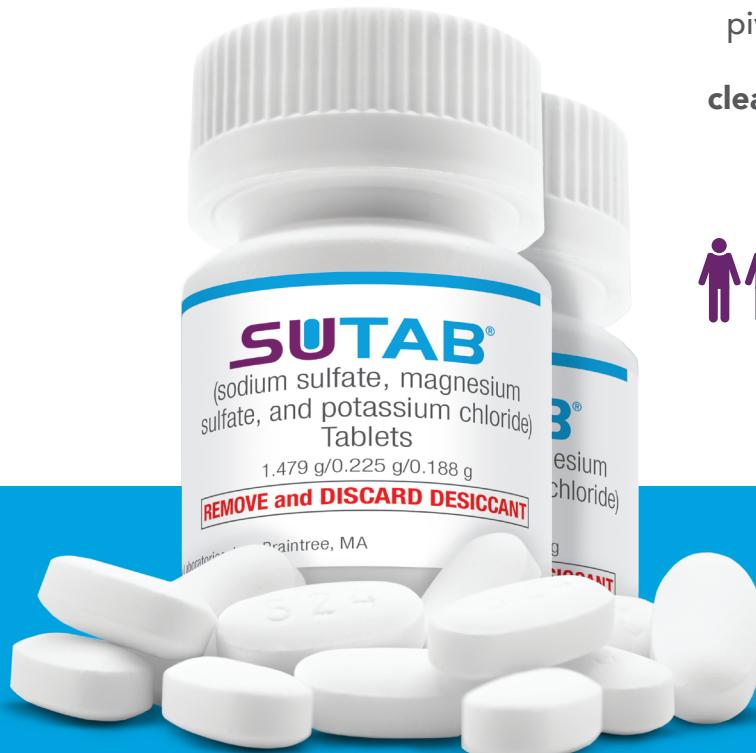
#### DRUG INTERACTIONS

Drugs that increase risk of fluid and electrolyte imbalance.

***Please see accompanying Full Prescribing Information and Medication Guide.***

1. Di Palma JA, Bhandari R, Cleveland M, et al. A safety and efficacy comparison of a new sulfate-based tablet bowel preparation versus a PEG and ascorbate comparator in adult subjects undergoing colonoscopy. *Am J Gastroenterol.* 2021;116(2):319-328. doi:10.14309/ajg.00000000000001020.
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4. Data on file. Braintree Laboratories, Inc. Braintree, MA.
5. Rex DK, Johnson DA, Anderson JC, et al; American College of Gastroenterology. American College of Gastroenterology guidelines for colorectal cancer screening 2009 [corrected]. *Am J Gastroenterol.* 2009;104(3):739-750.
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## Efficacy

92%

of patients in two pivotal trials **achieved successful bowel cleansing** with SUTAB<sup>1,2\*</sup>

## Compliance

98%

of patients in two pivotal trials were able to **complete both doses** of preparation<sup>1,2</sup>

## Tolerability

91%

of patients in one pivotal trial rated SUTAB as **tolerable to very easy to consume**<sup>1†</sup>



## Patient Acceptance

**Nearly 4 out of 5 patients (78%)** in one pivotal trial would request SUTAB again for a future colonoscopy<sup>1†</sup>

- **NO SODIUM PHOSPHATE<sup>2</sup>**
- **SAFE AND EFFECTIVE<sup>1,2</sup>**
- **ACG-RECOMMENDED SPLIT-DOSE REGIMENT<sup>5</sup>**

— Two SUTAB doses are required for a complete preparation<sup>2</sup>

**Dose 1** consists of 12 tablets and 16 oz of water

**Dose 2** consists of 12 tablets and 16 oz of water

Each dose is followed by two additional 16 oz of water

\*Success was the primary endpoint and was defined in non-inferiority trials as an overall cleansing assessment of 3 (good) or 4 (excellent) by the blinded endoscopist; scores were assigned following completion of the colonoscopy.

†Patients completed a preference questionnaire following completion of study drug to capture their perceptions of the preparation experience. This questionnaire has not undergone formal validation.

<sup>‡</sup>Patients were queried for selected gastrointestinal adverse reactions of upper abdominal pain, abdominal distention, nausea, and vomiting following completion of study drug, rating the intensity as mild, moderate, or severe.<sup>1,2</sup>

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