FULL PRESCRIBING INFORMATION

INDICATIONS AND USES

SUTAB is indicated for preparation before colonoscopy.

CONTRAINDICATIONS

SUTAB is contraindicated in the following conditions:

1. Patients with significant gastrointestinal disease
2. Patients with renal impairment
3. Patients with significant renal impairment
4. Patients with hepatic impairment

Do not take other laxatives while taking SUTAB.

DRUG INTERACTIONS

For complete information on preparation before colonoscopy and administration of the dosage regimen, see full prescribing information.

ADVERSE REACTIONS

1. Patients with significant gastrointestinal disease
2. Patients with renal impairment
3. Patients with significant renal impairment

PATIENT COUNSELING INFORMATION

SUTAB is contraindicated in the following conditions:

1. Patients with significant gastrointestinal disease
2. Patients with renal impairment
3. Patients with significant renal impairment

Severe fluid and electrolyte abnormalities were more commonly associated with SUTAB than treated with comparator in either Study 1 or Study 2 were: magnesium (27% SUTAB and 5% comparator) and potassium (8% SUTAB and 0% comparator) in Study 1, and potassium (8% SUTAB and 0% comparator) in Study 2.

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SUTAB is a prescription medicine used by adults to clean the colon before a colonoscopy.

What is the most important information I should know about SUTAB?

SUTAB cleans your colon by causing you to have diarrhea. Cleaning your colon helps your healthcare provider check or treat the inside of your colon. Tell your healthcare provider if you have a bowel condition that requires your healthcare provider to complete an accurate bowel preparation.)

SUTAB is given by mouth (oral) at least 6 hours before your colonoscopy and again before you start taking SUTAB.

SUTAB is taken using the Split-Dose method. Each carton of SUTAB (NDC 52268-201-01) contains:

• 25 tablets

Each tablet contains:

• 254 mg sodium sulfate, 90 mg potassium chloride, and 15 mg magnesium sulfate

Before taking SUTAB, tell your healthcare provider about any of your medical conditions, including:

• kidney problems
• heart problems
• lung problems
• liver problems
• problems with blood clots
• stomach ulcers
• any blood or stool that is black, tarry, or柏柏
• fever or chills
• trouble breathing
• seizures
• confusion
• feeling light-headed or faint
• heart palpitations
• severe dizziness
• chest pain
• uncontrolled high blood pressure
• swelling in your abdomen, legs, or feet

Tell your healthcare provider all about the medicine(s) you are taking. Include prescription and nonprescription medicines, vitamins, and herbal or homeopathic products. Tell your healthcare provider if you are pregnant or plan to become pregnant. You should not take SUTAB if you are pregnant or if you think you might be pregnant. There are no available data on SUTAB use in pregnant women to evaluate for a drug-associated risk of major birth defects.

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