

Sutab® (sodium sulfate/magnesium sulfate/potassium chloride) – New drug approval

- On November 10, 2020, [Sebelo Pharmaceuticals announced](#) the FDA approval of [Sutab \(sodium sulfate/magnesium sulfate/potassium chloride\)](#), for the cleansing of the colon as a preparation for colonoscopy in adults.
- Sutab is an osmotic laxative and cleaning the colon helps a healthcare provider see the inside of a colon more clearly during a colonoscopy.
- The efficacy of Sutab was established in two randomized, single-blind, active-controlled studies in adult patients undergoing colonoscopy for colorectal cancer screening and surveillance, or diagnostic colonoscopy. In study 1, 548 patients were randomized to one of the following two colon preparation regimens: Sutab or polyethylene glycol 3350, sodium sulfate, sodium chloride, potassium chloride, ascorbic acid and sodium ascorbate. In study 2, 388 patients were randomized to Sutab or sodium picosulfate, magnesium oxide, and anhydrous citric acid. The primary efficacy endpoint in each study was the proportion of patients with successful colon cleansing.
 - In both studies, Sutab was non-inferior to the comparator. In study 1, the difference in overall cleaning rate was 3.0 (99% CI: -3.2, 9.3) and in study 2 the difference was 3.1 (99% CI: -4.5, 10.7).
- Sutab is contraindicated in the following conditions:
 - Gastrointestinal obstruction or ileus
 - Bowel perforation
 - Toxic colitis or toxic megacolon
 - Gastric retention
- Warnings and precautions for Sutab include serious fluid and electrolyte abnormalities; cardiac arrhythmias; seizures; use in patients with risk of renal injury; colonic mucosal ulcerations and ischemic colitis; and use in patients with significant gastrointestinal disease.
- The most common adverse reactions with Sutab use were nausea, abdominal distension, vomiting and upper abdominal pain.
- Sutab requires administration of two doses (24 tablets) for a complete preparation for colonoscopy. Twelve (12) tablets are equivalent to one dose. Water must be consumed with each dose of Sutab and additional water must be consumed after each dose.
 - Refer to the Sutab drug label for complete dosing and administration recommendations.
- Braintree Laboratories will be marketing Sutab and they plan to launch the product on January 1, 2021. Sutab will be available as tablets containing 1.479 g sodium sulfate, 0.225 g magnesium sulfate, and 0.188 g potassium chloride.