

Pizensy[™] (lactitol) – New drug approval

- On February 12, 2020, the [FDA approved](#) Braintree Laboratories' [Pizensy \(lactitol\)](#), for chronic idiopathic constipation (CIC) in adults.
- Pizensy is an osmotic laxative. It works by causing the influx of water into the small intestine leading to a laxative effect in the colon.
- The efficacy of Pizensy was established in a double-blind, randomized, placebo-controlled study in 594 adult patients with symptoms of CIC. The efficacy of Pizensy was assessed using a responder analysis and change-from-baseline in the complete spontaneous bowel movements (CSBM) endpoint. The primary efficacy analysis was based on the first 12 weeks of the 6-month treatment period.
 - The responder rate was 25% and 13% for Pizensy and placebo, respectively (treatment difference: 12%, 95% CI: 6.0, 18.5; $p < 0.05$).
 - The Pizensy group had a mean increase of 0.8 CSBM/week from baseline to week 12 over the placebo group.
- In a second study, Pizensy was also compared to an active control ([Amitiza[®] \[lubiprostone\]](#)) in a double-blind, double-dummy design study in adult patient with symptoms of CIC. The primary endpoint was the same as the study above. The frequency of CSBMs/week for the Pizensy group was consistent with the results of the first study.
- Studies of varying design describing the efficacy of lactitol in increasing the frequency of bowel movements during short-term treatment of less than 4 weeks in patients with symptoms of CIC have also been published.
- Pizensy is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction or galactosemia.
- The most common adverse reactions ($\geq 3\%$) with Pizensy use were upper respiratory tract infection, flatulence, diarrhea, increased blood creatinine phosphokinase, abdominal distension, and increased blood pressure.
- The recommended dose of Pizensy is 20 grams orally once daily, preferably with meals.
 - The dosage can be reduced to 10 grams once daily for persistent loose stools.
- Braintree Laboratories' launch plans for Pizensy are pending. Pizensy will be available as a powder for oral solution supplied as 280 grams and 560 grams in multi-dose bottles, and 10 grams in unit-dose packets.