

## Pizensy<sup>™</sup> (lactitol) – New drug approval

- On February 12, 2020, the <u>FDA approved</u> Braintree Laboratories' <u>Pizensy (lactitol)</u>, 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 (<a href="Maitiza" [lubiprostone">Amitiza</a> [lubiprostone</a>]) 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 (≥ 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 unitdose packets.



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