**FDA NEWS RELEASE**

# FDA approves Trulance for Chronic Idiopathic Constipation

**For Immediate Release:**

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The U.S. Food and Drug Administration today approved Trulance (plecanatide) for the treatment of Chronic Idiopathic Constipation (CIC) in adult patients.

“No one medication works for all patients suffering from chronic gastrointestinal disorders,” said Julie Beitz, M.D., director of the Office of Drug Evaluation III in the FDA’s Center for Drug Evaluation and Research. “With the availability of new therapies, patients and their doctors can select the most appropriate treatment for their condition.”

According to the National Institutes of Health, an estimated 42 million people are affected by constipation. Chronic idiopathic constipation is a diagnosis given to those who experience persistent constipation and for whom there is no structural or biochemical explanation.

Trulance, taken orally once daily, works locally in the upper GI tract to stimulate secretion of intestinal fluid and support regular bowel function.

The safety and efficacy of Trulance were established in two 12-week, placebo-controlled trials including 1,775 adult participants. Participants were randomly assigned to receive a placebo or Trulance, once daily. Participants in the trials were required to have been diagnosed with constipation at least six months prior to the study onset and to have less than three defecations per week in the previous three months, as well as other symptoms associated with constipation. Participants receiving Trulance were more likely to experience improvement in the frequency of complete spontaneous bowel movements than those receiving placebo, and also had improvements in stool frequency and consistency and straining.

Trulance should not be used in children less than six years of age due to the risk of serious dehydration. Trulance should be avoided in patients six years of age to 18 years of age. The safety and effectiveness of Trulance have not been established in patients less than 18 years of age. Trulance should not be used in patients with known or suspected mechanical gastrointestinal obstruction.

The most common and serious side effects of Trulance was diarrhea. Patients may experience severe diarrhea. If severe diarrhea occurs, patients should stop taking Trulance and contact their health care provider.

Trulance is manufactured by New York, New York-based Synergy Pharmaceuticals Inc.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

## Related Information

- FDA Approved Drugs: Questions and Answers (/drugs/information-consumers-drugs/approved-drugs-questions-and-answers)
- NIH: Constipation (https://www.niddk.nih.gov/health-information/digestive-diseases/constipation)

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