

You are cordially invited to attend a lecture

featuring

IMTIAZ ALAM, M.D., P.A.

Gastroenterology & Hepatology Private Practice

Trulance™ (Plecanatide) for Adults with Chronic Idiopathic Constipation (CIC)

Tuesday, June 6, 2017, 6:30PM

McCormick & Schmick's Seafood & Steaks

11600 Century Oaks Terrace, Austin, TX 78758 512-836-0500

Please RSVP by Tuesday, May 30, 2017

RSVP to www.synergyrsvp.com Please reference SNG1422

For questions, contact your Synergy representative, Jennifer Ryan

Email: JRyan@synergypharma.com

Mobile: 512-751-3946

Attendance is limited to active, state-licensed healthcare professionals. Attendees will be required to provide their license number at the program. This invitation is not extended to certain specialties.

The Speaker is a Consultant engaged by Synergy Pharmaceuticals Inc.

Only HCPs with a legitimate professional interest, e.g. HCPs practicing in the therapeutic areas in which Synergy Products are approved, may attend a Speaker Program. Spouses, relatives, significant others, friends or other guests of HCPs may not attend.

Please see following page for Important Safety Information, including Box Warning.

Please also see accompanying full Prescribing Information.



Important Safety Information

WARNING: RISK OF SERIOUS DEHYDRATION IN PEDIATRIC PATIENTS

Trulance is contraindicated in patients less than 6 years of age; in nonclinical studies in young juvenile mice administration of a single oral dose of plecanatide caused deaths due to dehydration. Use of Trulance should be avoided in patients 6 years to less than 18 years of age. The safety and efficacy of Trulance have not been established in pediatric patients less than 18 years of age.

Contraindications

- Trulance is contraindicated in patients less than 6 years of age due to the risk of serious dehydration.
- Trulance is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction.

Warnings and Precautions

Risk of Serious Dehydration in Pediatric Patients

- Trulance is contraindicated in patients less than 6 years of age. The safety and effectiveness of Trulance in patients less than 18 years of age have not been established. In young juvenile mice (human age equivalent of approximately 1 month to less than 2 years), plecanatide increased fluid secretion as a consequence of stimulation of guanylate cyclase-C (GC-C), resulting in mortality in some mice within the first 24 hours, apparently due to dehydration. Due to increased intestinal expression of GC-C, patients less than 6 years of age may be more likely than older patients to develop severe diarrhea and its potentially serious consequences.
- Use of Trulance should be avoided in patients 6 years to less than 18 years of age. Although there were no deaths in older juvenile mice, given the deaths in young mice and the lack of clinical safety and efficacy data in pediatric patients, use of Trulance should be avoided in patients 6 years to less than 18 years of age.

Diarrhea

- Diarrhea was the most common adverse reaction in the two placebo-controlled clinical trials. Severe diarrhea was reported in 0.6% of patients.
- If severe diarrhea occurs, the health care provider should suspend dosing and rehydrate the patient.

Adverse Reactions

• In the two combined CIC clinical trials, the most common adverse reaction in Trulance-treated patients (incidence ≥2% and greater than in the placebo group) was diarrhea (5% vs 1% placebo).

Indication

Trulance (plecanatide) 3 mg tablets is indicated in adults for the treatment of chronic idiopathic constipation (CIC).

Please also see the <u>full Prescribing Information</u>.

References: 1. Trulance [package insert]. New York, NY: Synergy Pharmaceuticals Inc. 2. Data on file. Synergy Pharmaceuticals Inc. 2017.