The development and health benefits of TRULANCE have not been established in patients less than 18 years of age [see Contraindications (4), Use in Specific Populations (8.4)]. Avoid use of TRULANCE in patients 6 years to less than 18 years of age with rates in the clinical trials of another drug and may not reflect the rates in the population is unknown. All pregnancies have a background risk of birth defects (see Pregnancy Category C). While the risk of major birth defects with TRULANCE is not known, it is likely to be similar to the risk of major birth defects with other treatments for IBS-C with rates in the clinical trials of another drug and may not reflect the rates in the population is unknown. All pregnancies have a background risk of birth defects (see Pregnancy Category C). While the risk of major birth defects with TRULANCE is not known, it is likely to be similar to the risk of major birth defects with other treatments for IBS-C and its active metabolite bind to GC-C and act locally on the luminal surface of the gut, thereby increasing fluid-secretion into the gut lumen and decreasing stool consistency. The mechanism of action of plecanatide is not known.

In an animal model of visceral pain, plecanatide reduced abdominal muscle contractions. This effect is consistent with plecanatide’s proposed mechanism of action by activation of the cystic fibrosis transmembrane conductance regulator (CFTR) and the increased fluid-secretion into the gut lumen. In one nonclinical study in young juvenile mice administration of a single oral dose of 32 mg/kg of plecanatide significantly increased fluid-secretion into the gut lumen. This result is consistent with the proposed mechanism of action of plecanatide.

In a preclinical study in juvenile mice, plecanatide increased fluid-secretion into the gut lumen in a dose-dependent manner. This effect was not observed in nonclinical studies in juvenile mice administration of a single oral dose of 32 mg/kg of plecanatide significantly increased fluid-secretion into the gut lumen. This result is consistent with the proposed mechanism of action of plecanatide.

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What are the ingredients in TRULANCE?

Active ingredients:
- Plecanatide

Inactive ingredients: magnesium stearate and microcrystalline cellulose

Dosage and Administration

For patients treated with TRULANCE for the indication of chronic constipation (IBS-C, constipation-predominant) should be administered as a single oral dose once daily in the morning, with or without food [see Dosage and Administration (2.1)].

The efficacy of TRULANCE for the indication of chronic idiopathic constipation (IBS-C, constipation-predominant) was established in 2 clinical trials in patients with chronic constipation. In these studies, patients were randomized to either TRULANCE once daily (3 mg) or placebo for 12 weeks.

Inivalence for use in children below the age of 18 years has not been established.

Drug Interactions

Plecanatide and its active metabolite were not measurable in plasma following administration of the single 3-mg dose.

Elimination

The TRULANCE bottle contains a desiccant packet to help keep your medicine dry and a polyester coil to help protect the tablets during shipping. Remove the polyester coil from the bottle and throw it away.

Keep TRULANCE and all medicines out of the reach of children.

Safely throw away TRULANCE that is out of date or no longer needed.

-Store TRULANCE at room temperature between 65°F to 77°F (20°C to 25°C).
-Keep TRULANCE in its original bottle. Do not remove any tablets from the original bottle. Do not open any tablets from the bottle. Do not return any tablets to the bottle.

-Do not use rescue laxative (bisacodyl) within 72 hours before randomization.

-11% of patients treated with TRULANCE had spontaneous bowel movements (SBMs) of 13% or more per week for at least 6 months prior to diagnosis. Rome III criteria were modified to require at least 6 months prior to diagnosis.

-24% of patients report less than 3 defecations per week, rarely have a loose stool, and have a history of diarrhea;

-80% of patients are female, 70% are white, and 24% are black.

-22% of patients had a history of diarrhea. Patients with a history of diarrhea were excluded from the study.

-72% of patients treated with TRULANCE as compared to placebo.

-80% of patients treated with TRULANCE as compared to placebo.

-TRULANCE is effective for the management of symptoms of IBS-C.

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