TRULANCE is contraindicated in patients less than 6 years of age; avoid the use of TRULANCE in patients 6 years to less than 18 years of age. The safety and effectiveness of TRULANCE have not been established in patients younger than 6 years of age (see ADVERSE REACTIONS).

5.1 Risk of Serious Dehydration in Pediatric Patients

In clinical studies, deaths occurred in 3 of 1006 TRULANCE-treated patients (0.3%) and 3 of 1007 placebo-treated patients (0.3%). Deaths were due to dehydration in one trial; in the other two trials, deaths were due to dehydration and its potentially serious consequences. TRULANCE should not be used in patients with severe renal impairment (creatinine clearance ≤ 30 ml/min). TRULANCE is not recommended for use in patients with moderate to severe liver disease (Child-Pugh score ≥ 10) or carriers of the glucose-6-phosphate dehydrogenase deficiency gene, as these patients may be at increased risk for hemolytic anemia (see WARNINGS AND PRECAUTIONS).

The safety and effectiveness of TRULANCE in patients with moderate to severe chronic liver disease have not been established. In young juvenile mice (human age equivalent of approximately 6 months), the lack of clinical safety and efficacy data in pediatric patients, avoid the use of TRULANCE in patients 6 years to less than 18 years of age (see ADVERSE REACTIONS). The safety and effectiveness of TRULANCE in pediatric patients younger than 6 years of age have not been established. In young juvenile mice, deaths occurred within 24 hours in 1 of 40 TRULANCE-treated (2.5%) and 2 of 40 placebo-treated (5%) young juvenile mice. Deaths were due to dehydration and its potentially serious consequences. TRULANCE should not be used in patients with severe renal impairment (creatinine clearance ≤ 30 ml/min). TRULANCE is not recommended for use in patients with moderate to severe liver disease (Child-Pugh score ≥ 10) or carriers of the glucose-6-phosphate dehydrogenase deficiency gene, as these patients may be at increased risk for hemolytic anemia (see WARNINGS AND PRECAUTIONS).

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17  PATIENT COUNSELING INFORMATION

Do not give TRULANCE to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your doctor or pharmacist for information about TRULANCE that is written for health professionals.

What are the ingredients in TRULANCE?  
Active ingredients: plecanatide
Inactive ingredients: magnesium stearate and microcrystalline cellulose

TRULANCE is a trademark of Salix Pharmaceuticals, Inc. or its affiliates. This Medication Guide has been approved by the U.S. Food and Drug Administration. Revised: 02/2019

18 HOW SUPPLIED/STORAGE AND HANDLING

TRULANCE tablets are packaged in an aluminum foil blister pack of 30 in child-resistant packs of 30 in a foil lined carton (as measured daily) of at least 30% compared with baseline weekly average.

In clinical studies, study medication was administered without respect to food

Plecanatide had no effect on fertility or reproductive function in male or female mice. Impairment of Fertility

Animals administered plecanatide at doses up to 90 mg/kg/day or in rats at oral doses up to 100 mg/kg/day. Limited systemic exposure to plecanatide was achieved at the tested dose levels in animals, whereas no detectable exposure occurred in humans. Therefore, animal and human doses should be compared.

Neither plecanatide nor its active metabolite inhibited the cytochrome P450 (CYP) 3A4, 2C9, 2C19, 2D6, or 2C8/9 enzymes in vitro. In vivo CYP interactions have not been systematically studied. The effect of plecanatide on the CYP enzymes in vivo remains to be determined.

Termination of lactation.

TRULANCE is not recommended for use during pregnancy. It is not known whether plecanatide is excreted in human milk. Due to its known effects on human milk, the possible effects of plecanatide on the milk of breastfeeding women can be expected. It is advisable not to use TRULANCE during lactation.