



## MEET JENNIFER

### Presentation

- 42-year-old customer service supervisor
- Presents with complaints of constipation with moderate abdominal pain accompanied by the feeling of bloating for the past year (abdominal pain 5/10 on pain scale)
- Typically has a bowel movement once every 3-4 days with feelings of incomplete evacuation
- Hard, lumpy stools (2 on the Bristol Stool Form Scale) that require some straining to pass
- Reports having tried multiple therapies, including OTC and dietary modifications
- Diagnosed with IBS-C after physical and rectal exam with no red flags or alarm symptoms
- Reports that OTCs were mildly effective but did not provide any relief of her abdominal pain

### Treatment

- Prescribed Trulance 3 mg once daily to treat IBS-C, **to be taken at any time of day, with or without food**<sup>1</sup>

### Results

#### MORE regular, well-formed bowel movements

- Moved from a 2 to a 4 on the Bristol Stool Form Scale
- Improved from 2 spontaneous bowel movements per week before treatment to 5 spontaneous bowel movements
- Improved from 1 complete spontaneous bowel movement per week before treatment to 3 complete spontaneous bowel movements

#### LESS IBS-C-related abdominal pain

- Improvement in abdominal pain from a 5 on pain scale before treatment to a 2 (60% reduction)

#### LOW incidence of diarrhea

- Jennifer did not report any treatment-related diarrhea

After 12 weeks of treatment, Jennifer reported that her results were maintained.

***This profile is not an actual patient and results may vary.***

Do you have any patients who remind you of Jennifer?

### Indication

Trulance (plecanatide) 3 mg tablets is indicated in adults for the treatment of Chronic Idiopathic Constipation (CIC) and Irritable Bowel Syndrome with Constipation (IBS-C).

### 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.

## MEET SANDY

### Presentation

- 43-year-old high school math teacher
- Presents with constipation associated with abdominal pain
- Experiences an average of 2 spontaneous bowel movements per week; reports bloating, hard/lumpy stool that she identifies as a 1 on the Bristol Stool Form Scale, and “not feeling empty” after bowel movements
- Recently diagnosed with IBS-C after clinical interview, physical exam, and absence of alarm features
- Reports that IBS-C symptoms are unpredictable, causing her to leave work early or miss work with short notice
- Previously tried OTC laxatives that didn’t provide enough relief from constipation and IBS-related pain

### Treatment

- Prescribed Trulance 3 mg once daily to treat IBS-C, **to be taken at any time of day, with or without food**<sup>1</sup>
- Her insurance coverage required a prior authorization for Trulance, so her HCP visited [CoverMyMeds.com](https://www.covermymeds.com) for assistance and received approval

### Results

#### **MORE regular, well-formed bowel movements**

- Moved from a 1 to a 4 on the Bristol Stool Form Scale
- Improved from 2 spontaneous bowel movements per week before treatment to 5 spontaneous bowel movements
- Improved from 0 complete spontaneous bowel movements per week before treatment to 3 complete spontaneous bowel movements

#### **LESS IBS-C-related abdominal pain**

- Improvement in abdominal pain from a 6 on pain scale before treatment to a 3 (50% reduction)

After 12 weeks of treatment, Sandy reported that her results were maintained.

***This profile is not an actual patient and results may vary.***

Do you have any patients who remind you of Sandy?

### IMPORTANT SAFETY INFORMATION

#### 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.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including BOXED Warning.



## MEET LISA

### Presentation

- 48-year-old real estate agent
- Experiences only 4 bowel movements per week, with hard, “pebble-like” stools that are difficult to pass
- Reports straining but no abdominal pain associated with bowel movements
- Often feels like she “hasn’t completely finished going” and spends long periods on the toilet with “no success,” which interrupts her work
- Has tried OTC medications for constipation with minimal improvement and unwanted adverse events
- Diagnosed with CIC based on medical history and clinical exam

### Treatment

- Prescribed Trulance 3 mg once daily to treat CIC, **to be taken at any time of day, with or without food**<sup>1</sup>

### Results

#### **MORE regular, well-formed bowel movements**

- Moved from a 1 to a 4 on the Bristol Stool Form Scale
- Improved from 2 spontaneous bowel movements per week before treatment to 5 spontaneous bowel movements
- Improved from 1 complete spontaneous bowel movement per week before treatment to 3 complete spontaneous bowel movements

#### **LESS straining**

- Straining score reduced by 40%

After 12 weeks of treatment, Lisa reported that her results were maintained.

***This profile is not an actual patient and results may vary.***

Do you have any patients who remind you of Lisa?

## IMPORTANT SAFETY INFORMATION

### Warnings and Precautions (continued)

#### **Risk of Serious Dehydration in Pediatric Patients (continued)**

- 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 four placebo-controlled clinical trials for CIC and IBS-C. Severe diarrhea was reported in 0.6% of Trulance-treated CIC patients, and in 1% of Trulance-treated IBS-C patients.
- If severe diarrhea occurs, the health care provider should suspend dosing and rehydrate the patient.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including **BOXED Warning**.



Do you have any patients who remind you of John?

## MEET JOHN

### Presentation

- 54-year-old construction worker
- Experiences only 1-2 bowel movements per week over the last 2 years, with hard stools that he identifies as 1-2 on the Bristol Stool Form Scale
- <1 spontaneous bowel movement per week over the last 6 months
- Reports some straining but has no abdominal pain associated with bowel movements
- Never feels like he's "completely gone" after he's had a bowel movement
- Has taken several OTC medications, a stool softener, fiber, and laxatives—some of them in combination—with little to no results

### Treatment

- Prescribed Trulance 3 mg once daily to treat CIC, **to be taken at any time of day, with or without food**<sup>1</sup>
- Prescription was covered by his commercial insurance plan. After presenting a **Trulance Savings Card**, his copay was reduced to \$25

### Results

#### **MORE regular, well-formed bowel movements**

- Moved from a 2 to a 4 on the Bristol Stool Form Scale
- Improved from <1 spontaneous bowel movement per week before treatment to 4 spontaneous bowel movements
- Improved from 0 complete spontaneous bowel movements per week before treatment to 3 complete spontaneous bowel movements

After 12 weeks of treatment, John reported that his results were maintained.

***This profile is not an actual patient and results may vary.***

## IMPORTANT SAFETY INFORMATION

### Adverse Reactions

- In the two combined CIC clinical trials, the most common adverse reaction in Trulance-treated patients (incidence  $\geq 2\%$  and greater than in the placebo group) was diarrhea (5% vs 1% placebo).
- In the two combined IBS-C clinical trials, the most common adverse reaction in Trulance-treated patients (incidence  $\geq 2\%$  and greater than in the placebo group) was diarrhea (4.3% vs 1% placebo).

**Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including BOXED Warning.**

**Reference: 1.** Trulance [package insert]. Bridgewater, NJ: Salix Pharmaceuticals, 2019.

Trulance is a trademark of Salix Pharmaceuticals.

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**HIGHLIGHTS OF PRESCRIBING INFORMATION:**  
These highlights do not include all the information needed to use **TRULANCE** safely and effectively. See full prescribing information for **TRULANCE**.

**TRULANCE**® (plecanatide) tablets, for oral use  
Initial U.S. Approval: 2017

<p><b>WARNING: RISK OF SERIOUS DEHYDRATION IN PEDIATRIC PATIENTS</b> <i>See full prescribing information for complete boxed warning.</i></p> <ul style="list-style-type: none"><li><b>TRULANCE</b> is contraindicated in patients less than 6 years of age; in young juvenile mice, plecanatide caused death due to dehydration. (4, 8.4)</li><li><b>Avoid use of TRULANCE</b> in patients 6 years to less than 18 years of age. (5.1, 8.4)</li><li><b>The safety and effectiveness of TRULANCE have not been established in patients less than 18 years of age. (8.4)</b></li></ul>
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-----**DOSAGE FORMS AND STRENGTHS**-----  
Tablets: 3 mg (3)  
-----**CONTRAINDICATIONS**-----

- Patients less than 6 years of age due to the risk of serious dehydration. (4, 5.1, 8.4)
- Patients with known or suspected mechanical gastrointestinal obstruction. (4)

-----**WARNINGS AND PRECAUTIONS**-----  
Diarrhea: Patients may experience severe diarrhea. If severe diarrhea occurs, suspend dosing and rehydrate the patient. (5.2)  
-----**ADVERSE REACTIONS**-----  
Most common adverse reaction (≥2%) is diarrhea. (6.1)  
**To report SUSPECTED ADVERSE REACTIONS, contact Salix Pharmaceuticals at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. See 17 for PATIENT COUNSELING INFORMATION and Medication Guide. Revised: 02/2020**

-----**INDICATIONS AND USAGE**-----  
TRULANCE is a guanylate cyclase-C agonist indicated in adults for treatment of:

- chronic idiopathic constipation (CIC). (1)
- irritable bowel syndrome with constipation (IBS-C). (1)

-----**DOSAGE AND ADMINISTRATION**-----  
The recommended adult dosage of TRULANCE is

- CIC: 3 mg taken orally once daily. (2.1)
- IBS-C: 3 mg taken orally once daily. (2.1)

**FULL PRESCRIBING INFORMATION: CONTENTS\***  
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**FULL PRESCRIBING INFORMATION**

<p><b>WARNING: RISK OF SERIOUS DEHYDRATION IN PEDIATRIC PATIENTS</b> <b>TRULANCE</b> 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 [<i>see Contraindications (4), Use in Specific Populations (8.4)</i>].</p> <ul style="list-style-type: none"><li><b>Avoid use of TRULANCE</b> in patients 6 years to less than 18 years of age [<i>see Warnings and Precautions (5.1), Use in Specific Populations (8.4)</i>].</li><li><b>The safety and effectiveness of TRULANCE have not been established in patients less than 18 years of age</b> [<i>see Use in Specific Populations (8.4)</i>].</li></ul>
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**1 INDICATIONS AND USAGE**  
TRULANCE is indicated in adults for the treatment of:

- chronic idiopathic constipation (CIC).
- irritable bowel syndrome with constipation (IBS-C)

**2 DOSAGE AND ADMINISTRATION**

**2.1 Recommended Dosage**  
The recommended dosage of TRULANCE for the treatment of CIC and IBS-C is 3 mg taken orally once daily.

**2.2 Preparation and Administration Instructions**

- Take TRULANCE with or without food [*see Clinical Pharmacology (12.3)*].
- If a dose is missed, skip the missed dose and take the next dose at the regular time. Do not take two doses at the same time.
- Swallow a tablet whole for each dose.
- For adult patients with swallowing difficulties, TRULANCE tablets can be crushed and administered orally either in applesauce or with water or administered with water via a nasogastric or gastric feeding tube. Mixing TRULANCE crushed tablets in other soft foods or in other liquids has not been tested.

**Oral Administration in Applesauce:**

- In a clean container, crush the TRULANCE tablet to a powder and mix with 1 teaspoonful of room temperature applesauce.
- Consume the entire tablet-applesauce mixture immediately. Do not store the mixture for later use.

**Oral Administration in Water:**

- Place the TRULANCE tablet in a clean cup.
- Pour approximately 30 mL of room temperature water into the cup.
- Mix by gently swirling the tablet and water mixture for at least 10 seconds. The TRULANCE tablet will fall apart in the water.
- Swallow the entire contents of the tablet water mixture immediately.
- If any portion of the tablet is left in the cup, add another 30 mL of water to the cup, swirl for at least 10 seconds, and swallow immediately.
- Do not store the tablet-water mixture for later use.

**Administration with Water via a Nasogastric or Gastric Feeding Tube:**

- Place the TRULANCE tablet in a clean cup with 30 mL of room temperature water.
- Mix by gently swirling the tablet and water mixture for at least 15 seconds. The TRULANCE tablet will fall apart in the water.

**Administration Instructions (2.2):**

- Take with or without food.
- Swallow tablets whole.
- For patients who have difficulty swallowing tablets whole or those with a nasogastric or gastric feeding tube, see full prescribing information with instructions for crushing the tablet and administering with applesauce or water.

-----**DOSAGE FORMS AND STRENGTHS**-----  
Tablets: 3 mg (3)  
-----**CONTRAINDICATIONS**-----

- Patients less than 6 years of age due to the risk of serious dehydration. (4, 5.1, 8.4)
- Patients with known or suspected mechanical gastrointestinal obstruction. (4)

-----**WARNINGS AND PRECAUTIONS**-----  
Diarrhea: Patients may experience severe diarrhea. If severe diarrhea occurs, suspend dosing and rehydrate the patient. (5.2)  
-----**ADVERSE REACTIONS**-----  
Most common adverse reaction (≥2%) is diarrhea. (6.1)  
**To report SUSPECTED ADVERSE REACTIONS, contact Salix Pharmaceuticals at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. See 17 for PATIENT COUNSELING INFORMATION and Medication Guide. Revised: 02/2020**

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**2.1 Recommended Dosage**  
The recommended dosage of TRULANCE for the treatment of CIC and IBS-C is 3 mg taken orally once daily.

**2.2 Preparation and Administration Instructions**

- Take TRULANCE with or without food [*see Clinical Pharmacology (12.3)*].
- If a dose is missed, skip the missed dose and take the next dose at the regular time. Do not take two doses at the same time.
- Swallow a tablet whole for each dose.
- For adult patients with swallowing difficulties, TRULANCE tablets can be crushed and administered orally either in applesauce or with water or administered with water via a nasogastric or gastric feeding tube. Mixing TRULANCE crushed tablets in other soft foods or in other liquids has not been tested.

**Oral Administration in Applesauce:**

- In a clean container, crush the TRULANCE tablet to a powder and mix with 1 teaspoonful of room temperature applesauce.
- Consume the entire tablet-applesauce mixture immediately. Do not store the mixture for later use.

**Oral Administration in Water:**

- Place the TRULANCE tablet in a clean cup.
- Pour approximately 30 mL of room temperature water into the cup.
- Mix by gently swirling the tablet and water mixture for at least 10 seconds. The TRULANCE tablet will fall apart in the water.
- Swallow the entire contents of the tablet water mixture immediately.
- If any portion of the tablet is left in the cup, add another 30 mL of water to the cup, swirl for at least 10 seconds, and swallow immediately.
- Do not store the tablet-water mixture for later use.

**Administration with Water via a Nasogastric or Gastric Feeding Tube:**

- Place the TRULANCE tablet in a clean cup with 30 mL of room temperature water.
- Mix by gently swirling the tablet and water mixture for at least 15 seconds. The TRULANCE tablet will fall apart in the water.

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- chronic idiopathic constipation (CIC).
- irritable bowel syndrome with constipation (IBS-C)

**2 DOSAGE AND ADMINISTRATION**

**2.1 Recommended Dosage**  
The recommended dosage of TRULANCE for the treatment of CIC and IBS-C is 3 mg taken orally once daily.

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- Swallow a tablet whole for each dose.
- For adult patients with swallowing difficulties, TRULANCE tablets can be crushed and administered orally either in applesauce or with water or administered with water via a nasogastric or gastric feeding tube. Mixing TRULANCE crushed tablets in other soft foods or in other liquids has not been tested.

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**1 INDICATIONS AND USAGE**  
TRULANCE is indicated in adults for the treatment of:

- chronic idiopathic constipation (CIC).
- irritable bowel syndrome with constipation (IBS-C)

**2 DOSAGE AND ADMINISTRATION**

**2.1 Recommended Dosage**  
The recommended dosage of TRULANCE for the treatment of CIC and IBS-C is 3 mg taken orally once daily.

**2.2 Preparation and Administration Instructions**

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**Medication Guide**  
**TRULANCE® (TROO lans)**  
**(plecanatide) tablets**

**What is the most important information I should know about TRULANCE?**

- Do not give TRULANCE to children who are less than 6 years of age. It may harm them.**
- You should not give TRULANCE to children 6 years to less than 18 years of age. It may harm them.**

See **“What are the possible side effects of TRULANCE?”** for more information about side effects.

**What is TRULANCE?**  
TRULANCE is a prescription medicine used in adults to treat:

- a type of constipation called chronic idiopathic constipation (CIC). Idiopathic means the cause of the constipation is unknown.
- irritable bowel syndrome with constipation (IBS-C).

**It is not known if TRULANCE is safe and effective in children less than 18 years of age.**

**Who should not take TRULANCE?**

- Do not give TRULANCE to children who are less than 6 years of age.**
- Do not take TRULANCE if a doctor has told you that you have a bowel blockage (intestinal obstruction).

**Before taking TRULANCE, tell your doctor about all of your medical conditions, including if you:**

- are pregnant or plan to become pregnant. It is not known if TRULANCE will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if TRULANCE passes into your breast milk. Talk with your doctor about the best way to feed your baby if you take TRULANCE.

**Tell your doctor about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

**How should I take TRULANCE?**

- Take TRULANCE exactly as your doctor tells you to take it.
- Take TRULANCE by mouth, 1 time each day with or without food.
- If you miss a dose, skip the missed dose. Take the next dose at your regular time. Do not take 2 doses at the same time.
- TRULANCE tablets should be swallowed whole.
  - Adults who cannot swallow TRULANCE tablets whole may crush the TRULANCE tablet and mix with applesauce or dissolve TRULANCE in water before swallowing. TRULANCE tablets may also be taken with water by adults through a nasogastric or gastric feeding tube.

It is not known if TRULANCE is safe and effective when crushed and mixed with other foods or dissolved in other liquids.

**Taking TRULANCE in applesauce:**

- Crush the TRULANCE tablet in a clean container until it is a powder and mix with 1 teaspoon of room temperature applesauce.
- Swallow all of the TRULANCE and applesauce mixture right away. Do not keep the TRULANCE and applesauce mixture for future use.

**Taking TRULANCE in water:**

- Place the TRULANCE tablet in a clean cup and pour 1 ounce (30 mL) of room temperature water into the cup.
- Gently swirl the TRULANCE tablet and water for at least 10 seconds. The TRULANCE tablet will fall apart in the water.
- Swallow all of the TRULANCE tablet and water mixture right away. Do not keep the mixture for future use.
- If you see any part of the tablet left in the cup, add another 1 ounce (30 mL) of water to the cup, swirl for at least 10 seconds, and swallow right away.

**Taking TRULANCE through a nasogastric or gastric feeding tube:**  
Gather the supplies you will need to take your TRULANCE dose. Your doctor should tell you what size catheter tip syringe you will need for your dose. Ask your doctor if you have any questions about how to give TRULANCE the right way.

- Place the TRULANCE tablet in a clean cup with 1 ounce (30 mL) of room temperature water.
- Gently swirl the TRULANCE tablet and water for at least 15 seconds. The TRULANCE tablet will fall apart in the water.
- Flush the nasogastric or gastric feeding tube with 1 ounce (30 mL) of water.
- Draw up the TRULANCE tablet and water mixture into a catheter tip syringe and give right away through the nasogastric or gastric feeding tube. Do not keep the mixture for future use.
- If you see any part of the tablet left in the cup, add another 1 ounce (30 mL) of water to the cup, swirl for at least 15 seconds and use the same catheter tip syringe to give the mixture through the nasogastric or gastric feeding tube.
- Using the same or another catheter tip syringe, flush the nasogastric or gastric feeding tube with at least 10 mL of water.

**What are the possible side effects of TRULANCE?**  
**TRULANCE can cause serious side effects, including:**

- See **“What is the most important information I should know about TRULANCE?”**
- Diarrhea is the most common side effect of TRULANCE, and it can sometimes be severe.**
  - Diarrhea often begins within the first 4 weeks of TRULANCE treatment.

**Stop taking TRULANCE and call your doctor if you develop severe diarrhea.**  
These are not all the possible side effects of TRULANCE.  
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Revised: 02/2020  
Prescribing Information  
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TRULANCE® (TROO lans)  
(plecanatide) tablets

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## How should I store TRULANCE?

- Store TRULANCE at room temperature between 68° to 77°F (20° to 25°C).
- Keep TRULANCE in a secure place and in the bottle or blister pack that it comes in.
- The TRULANCE bottle contains a desiccant packet to help keep your medicine dry (protect it from moisture). Do not remove the desiccant packet from the bottle.
- The TRULANCE bottle contains a polyester coil to help protect the tablets during shipping. Remove the polyester coil from the bottle and throw it away after opening the bottle.
- Keep the container of TRULANCE tightly closed and in a dry place.
- Safely throw away TRULANCE that is out of date or no longer needed.

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

### General information about the safe and effective use of TRULANCE.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use TRULANCE for a condition for which it was not prescribed. 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 ingredient:** plecanatide

**Inactive ingredients:** magnesium stearate and microcrystalline cellulose

#### Distributed by:

Salix Pharmaceuticals, a division of  
Bausch Health US, LLC  
Bridgewater, NJ 08807 USA

U.S. Patent Numbers: 7,041,786; 7,799,897; 8,637,451; 9,610,321; 9,616,097; 9,919,024; 9,925,231 and 10,011,637

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Revised: 02/2020

#### Elimination

#### Metabolism

Plecanatide was metabolized in the GI tract to an active metabolite by loss of the terminal leucine moiety. Both plecanatide and the metabolite were proteolytically degraded within the intestinal lumen to smaller peptides and naturally occurring amino acids.

#### Excretion

No excretion studies have been conducted in humans. Plecanatide and its active metabolite were not measurable in plasma following administration of the recommended clinical doses.

#### Drug Interaction Studies

Neither plecanatide nor its active metabolite inhibited the cytochrome P450 (CYP) enzymes 2C9 and 3A4, and they did not induce CYP3A4 in vitro.

Plecanatide and its active metabolite were neither substrates nor inhibitors of the transporters P-glycoprotein (P-gp) or breast cancer resistance protein (BCRP) in vitro.

### 13 NONCLINICAL TOXICOLOGY

#### 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

##### Carcinogenesis

The carcinogenic potential of plecanatide was assessed in 2-year carcinogenicity studies in mice and rats. Plecanatide was not tumorigenic in mice at oral 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 not be compared directly for evaluating relative exposure.

##### Mutagenesis

Plecanatide was not genotoxic in the in vitro bacterial reverse mutation (Ames) assay, in vitro mouse lymphoma mutation assay, or the in vivo mouse bone marrow micronucleus assay.

##### Impairment of Fertility

Plecanatide had no effect on fertility or reproductive function in male or female mice at oral doses of up to 600 mg/kg/day.

### 14 CLINICAL STUDIES

#### 14.1 Chronic Idiopathic Constipation (CIC)

The efficacy of TRULANCE for the management of symptoms of CIC was established in two 12-week, double-blind, placebo-controlled, randomized, multicenter clinical studies in adult patients (Study 1 and Study 2). In the Intention-to-Treat (ITT) population, a total of 905 patients (Study 1) and 870 patients (Study 2) were randomized 1:1 to either placebo or TRULANCE 3 mg, once daily. In clinical studies, study medication was administered without respect to food intake. Demographics for these studies included an overall mean age of 45 years (range 18 to 80 years), 80% female, 72% white, and 24% black.

To be eligible for the studies, patients were required to meet modified Rome III criteria for at least 3 months prior to the screening visit, with symptom onset for at least 6 months prior to diagnosis. Rome III criteria were modified to require that patients report less than 3 defecations per week, rarely have a loose stool without the use of laxatives, not use manual maneuvers to facilitate defecations, and not meet criteria for IBS-C. In addition, patients were required to report at least two of the following symptoms:

- Straining during at least 25% of defecations
- Lumpy or hard stool in at least 25% of defecations
- Sensation of incomplete evacuations for at least 25% of defecations
- Sensation of anorectal obstruction/blockage for at least 25% of defecations

Patients who met these criteria were also required to demonstrate the following during the last 2 weeks of the screening period:

- Less than 3 complete spontaneous bowel movements (CSBMs) (a CSBM is an SBM that is associated with a sense of complete evacuation) in each of the two weeks
- Bristol Stool Form Scale (BSFS) of 6 or 7 in less than 25% of spontaneous bowel movements (SBMs) (an SBM is a bowel movement occurring in the absence of laxative use)
- One out of the following three:
  - BSFS of 1 or 2 in at least 25% of defecations
  - A straining value recorded on at least 25% of days when a BM was reported
  - At least 25% of BMs result in a sense of incomplete evacuation

The efficacy of TRULANCE was assessed using a responder analysis and change-from-baseline in CSBM and SBM endpoints. Efficacy was assessed using information provided by patients on a daily basis in an electronic diary.

A responder was defined as a patient who had at least 3 CSBMs in a given week and an increase of at least 1 CSBM from baseline in the same week for at least 9 weeks out of the 12 week treatment period and at least 3 of the last 4 weeks of the study. The responder rates are shown in Table 3.

**Table 3: Efficacy Responder Rates in the Two Placebo-controlled Studies of CIC: at least 9 of 12 weeks and at least 3 of the last 4 weeks (ITT Population)**

Study 1			
	TRULANCE 3 mg N = 453	Placebo N = 452	Treatment Difference <sup>a</sup> [95% CI <sup>b</sup> ]
Responder <sup>c</sup>	21%	10%	11% [6.1%, 15.4%]
Study 2			
	TRULANCE 3 mg N = 430	Placebo N = 440	Treatment Difference <sup>a</sup> [95% CI <sup>b</sup> ]
Responder <sup>c</sup>	21%	13%	8% [2.6%, 12.4%]

<sup>a</sup> p-value <0.005

<sup>b</sup> CI = confidence interval

<sup>c</sup> Primary endpoint defined as a patient who had at least 3 CSBMs in a given week and an increase of at least 1 CSBM from baseline in the same week for at least 9 weeks out of the 12 week treatment period and at least 3 of the last 4 weeks of the study.

In both studies, improvements in the frequency of CSBMs/week were seen as early as week 1 with improvement maintained through week 12. The difference between the TRULANCE group and the placebo group in the mean change of CSBMs/week frequency from baseline to week 12 was approximately 1.1 CSBMs/week.

Over the 12 week treatment period, improvements were observed in stool frequency (number of CSBMs/week and SBMs/week) and/or stool consistency (as measured by the BSFS), and/or in the amount of straining with bowel movements (amount of time pushing or physical effort to pass stool) in the TRULANCE group as compared to placebo.

Following completion of the study drug treatment period, patients continued to record data in the daily diary for a 2 week Post-Treatment Period. During this time, TRULANCE-treated patients generally returned to baseline for these study endpoints.

In Studies 1 and 2, a third randomized treatment arm of TRULANCE 6 mg once daily did not demonstrate additional treatment benefit and had a greater incidence of adverse reactions than TRULANCE 3 mg once daily. Therefore, TRULANCE 6 mg once daily is not recommended [see *Dosage and Administration* (2.1)].

#### 14.2 Irritable Bowel Syndrome with Constipation (IBS-C)

The efficacy of TRULANCE for the management of symptoms of IBS-C was established in two 12-week, double-blind, placebo-controlled, randomized, multicenter clinical studies in adult patients (Study 3 and Study 4). In the Intention-to-Treat (ITT) population, a total of 699 patients (Study 3) and 754 patients (Study 4) received treatment with placebo or TRULANCE 3 mg once daily. In clinical studies, study medication was administered without respect to food intake. Demographics for these studies included an overall mean age of 44 years (range 18 to 83 years), 74% female, 73% white, and 22% black.

To be eligible, patients were required to meet the Rome III criteria for IBS for at least 3 months prior to the screening visit, with symptom onset for at least 6 months prior to diagnosis. Diagnosis required recurrent abdominal pain or discomfort at least 3 days/month in the last 3 months associated with 2 or more of 1) improvement with defecation, 2) onset associated with a change in frequency of stool, and 3) onset associated with a change in form (appearance) of stool. Patients also met the IBS-C differentiation criteria for constipation, characterized by a stool pattern such that at least 25% of defecations are hard or lumpy stools and no more than 25% of defecations are loose or watery stool.

Patients who met these criteria were excluded if they demonstrated the following during the last 2 weeks of the screening period:

- Worst abdominal pain intensity (WAPI) score of 0 on an 11-point scale for more than 2 days during each week
- An average WAPI of less than 3 for either week
- More than 3 complete spontaneous bowel movements (CSBMs) or more than six spontaneous bowel movements (SBMs) per week in either week
- Bristol Stool Form Scale (BSFS) of 7 for any SBM recorded
- More than 1 day in either week with a BSFS of 6 for any SBM recorded
- No use of rescue laxative (bisacodyl) within 72 hours before randomization

The efficacy of TRULANCE was assessed using a responder analysis based on abdominal pain intensity and a stool frequency responder (CSBM) endpoint. Efficacy was assessed using information provided by patients on a daily basis through an electronic phone diary system.

A responder was defined as a patient who met both the abdominal pain intensity and stool frequency responder criteria in the same week for at least 6 of the 12 treatment weeks. The abdominal pain intensity and stool frequency responder criteria assessed each week were defined as:

- Abdominal pain intensity responder: a patient who experienced a decrease in the weekly average of worst abdominal pain in the past 24 hours score (measured daily) of at least 30% compared with baseline weekly average.
- Stool frequency responder: a patient who experienced an increase of at least 1 CSBM per week from baseline.

The responder rates are shown in Table 4.

**Table 4: Efficacy Responder Rates in the Two Placebo-controlled Studies of IBS-C: Overall Responder for at Least 6 of the 12 Treatment Weeks (ITT Population)**

Study 3			
	Placebo N = 350	TRULANCE 3 mg N = 349	Treatment Difference [95% CI <sup>a</sup> ]
Responder <sup>b</sup>	18%	30%	12% [6%, 18%]
Components of Responder Endpoint			
Abdominal Pain Responder <sup>c</sup>	32%	41%	
CSBM Responder <sup>d</sup>	35%	48%	
Study 4			
	Placebo N = 379	TRULANCE 3 mg N = 375	Treatment Difference [95% CI <sup>a</sup> ]
Responder <sup>b</sup>	14%	21%	7% [2%, 13%]
Components of Responder Endpoint			
Abdominal Pain Responder <sup>c</sup>	23%	33%	
CSBM Responder <sup>d</sup>	28%	34%	

<sup>a</sup> CI = confidence interval

<sup>b</sup> A responder for these trials was defined as a patient who met both the abdominal pain and CSBM weekly responder criteria for at least 6 of the 12 weeks.

<sup>c</sup> An abdominal pain responder was defined as a patient who met the criteria of at least 30% reduction from baseline in weekly average of the worst daily abdominal pain, for at least 6 of the 12 weeks.

<sup>d</sup> A CSBM responder was defined as a patient who achieved an increase in at least 1 CSBM per week, from baseline, for at least 6 of 12 weeks.

In both studies, the proportion of responders who were also weekly responders for at least 2 of the 4 treatment weeks in month 3, the last month of treatment was greater in the TRULANCE groups compared to placebo.

Over the 12 week treatment period, improvements were observed in both stool consistency (as measured by the BSFS) and in the amount of straining with bowel movements (amount of time pushing or physical effort to pass stool) in the 3 mg TRULANCE group as compared to placebo.

Following completion of the study drug treatment period, patients continued to record data in the daily diary for a 2-week Post-Treatment Period. During this time, TRULANCE-treated patients generally returned to baseline for these study endpoints.

In Studies 3 and 4, a third randomized treatment arm of TRULANCE 6 mg once daily did not demonstrate additional treatment benefit over the 3 mg dose. Therefore, TRULANCE 6 mg once daily is not recommended [see *Dosage and Administration* (2.1)].

## 16 HOW SUPPLIED/STORAGE AND HANDLING

TRULANCE tablets are packaged in an aluminum foil unit dose blister pack of 30 in a child-resistant pack or in a white, opaque, high-density polyethylene round bottle with a screw-top polypropylene child-resistant cap and heat-activated induction seal. Each bottle container-closure system also contains a desiccant and a polyester coil.

TRULANCE 3 mg tablets are white to off-white, plain and round, debossed with “SP” on one side and “3” for 3 mg on the other side and supplied as:

NDC Number	Size
65649-003-30	Bottle of 30
70194-003-30	Aluminum foil unit dose blister pack of 30 in a child-resistant pack

Store at room temperature, 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Keep TRULANCE in a dry place. Protect from moisture. For bottles, keep TRULANCE in the original bottle. Do not remove desiccant from the bottle. Do not subdivide or repackage.

## 17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide).

Advise patients:

#### Diarrhea

To stop TRULANCE and contact their healthcare provider if they experience severe diarrhea [see *Warnings and Precautions* (5.2)].

#### Accidental Ingestion

Accidental ingestion of TRULANCE in children, especially in children less than 6 years of age, may result in severe diarrhea and dehydration. Instruct patients to take steps to store TRULANCE securely and out of reach of children and to dispose of unused TRULANCE [see *Contraindications* (4), *Warnings and Precautions* (5.2)].

#### Administration and Handling Instructions

- To take TRULANCE once daily with or without food [see *Dosage and Administration* (2.2)].
- If a dose is missed, skip the missed dose and take the next dose at the regular time. Do not take two doses at the same time.
- To swallow TRULANCE tablets whole.
- If adult patients have swallowing difficulties, TRULANCE tablets can be crushed and administered orally in either applesauce or with water, or administered with water via a nasogastric or gastric feeding tube, as described in the Medication Guide.

- To keep TRULANCE in a dry place. Protect from moisture. For bottles, keep TRULANCE in the original bottle. Do not remove desiccant from the bottle. Do not subdivide or repackage. Remove and discard polyester coil after opening. Keep bottles closed tightly [see *How Supplied/Storage and Handling* (16)].

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Bridgewater, NJ 08807 USA

U.S. Patent Numbers: 7,041,786; 7,799,897; 8,637,451; 9,610,321; 9,616,097; 9,919,024; 9,925,231 and 10,011,637

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