Trulance

(plecanatide)

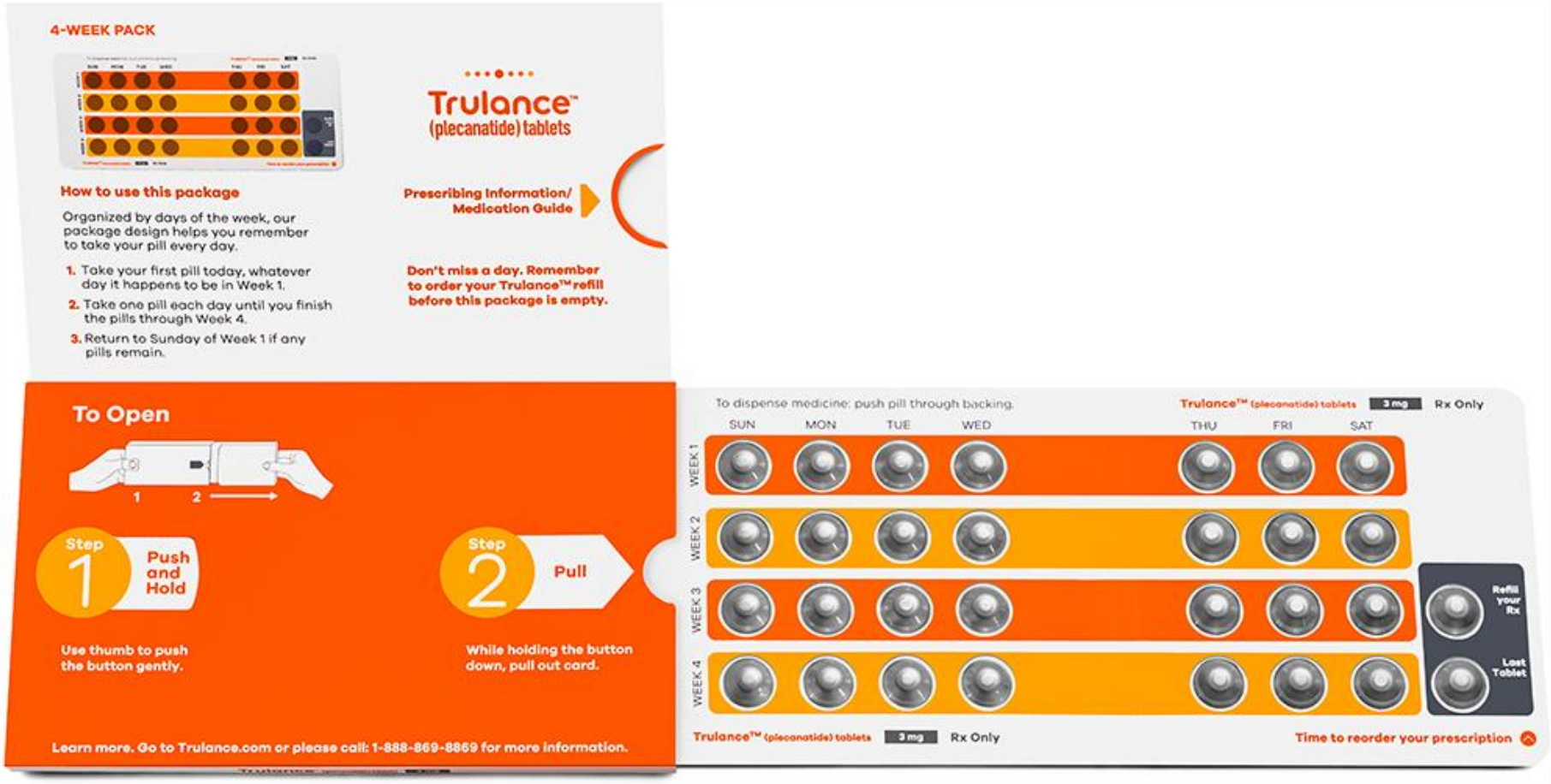
New Product Slideshow

MPR

Introduction

- **Brand name:** Trulance
- **Generic name:** Plecanatide
- **Pharmacological class:** Guanylate cyclase-C agonist
- **Strength and Formulation:** 3mg; tablets
- **Manufacturer:** Synergy
- **How supplied:** Bottle—30
- **Legal Classification:** Rx

Trulance


4-WEEK PACK
Trulance™
(plecanatide) tablets
How to use this package
Organized by days of the week, our package design helps you remember to take your pill every day.
1. Take your first pill today, whatever day it happens to be in Week 1.
2. Take one pill each day until you finish the pills through Week 4.
3. Return to Sunday of Week 1 if any pills remain.
Prescribing Information/ Medication Guide
Don't miss a day. Remember to order your Trulance™ refill before this package is empty.
To Open
1
2
Step 1 Push and Hold
Use thumb to push the button gently.
Step 2 Pull
While holding the button down, pull out card.
Learn more. Go to Trulance.com or please call: 1-888-869-8869 for more information.
To dispense medicine: push pill through backing.
Trulance™ (plecanatide) tablets 3 mg Rx Only
SUN MON TUE WED THU FRI SAT
WEEK 1
WEEK 2
WEEK 3
WEEK 4
Refill your Rx
Last Tablet
Trulance™ (plecanatide) tablets 3 mg Rx Only
Time to reorder your prescription

Indications

- Chronic idiopathic constipation (CIC)

Dosage & Administration

- Swallow whole; if difficulties in swallowing, may crush and mix in applesauce or water; may also give via NG or gastric feeding tube

- **≥18yrs:** 3mg once daily

Considerations for Special Populations

- **Pregnancy:** Insufficient data to inform any drug-associated risks for major birth defects and miscarriage
- **Nursing mothers:** Consider maternal need and any potential adverse effects on infant
- **Pediatric:** <18yrs: not established
  - <6yrs: contraindicated
  - 6–<18yrs: avoid
- **Elderly:** Insufficient number of subjects included in studies

Contraindications

- Children <6 years old
- Known or suspected mechanical GI obstruction

Warnings/Precautions

- Suspend dosing and rehydrate if severe diarrhea occurs
- Pregnancy
- Nursing mothers

Adverse Reactions

- Diarrhea (may be severe)
- Sinusitis
- Upper respiratory tract infection
- Abdominal distension
- Flatulence
- Abdominal tenderness
- Increased liver enzymes

Mechanism of Action

- Plecanatide functions as a guanylate cyclase-C (GC-C) agonist
- Activation of GC-C results in an increase in both intracellular and extracellular concentrations cGMP
- Elevation of intracellular cGMP stimulates secretion of chloride and bicarbonate into the intestinal lumen, mainly through activation of the CFTR ion channel, resulting in increased intestinal fluid and accelerated transit

Clinical Trials

- The efficacy of Trulance was established in two, 12-week, double-blind, placebo-controlled, randomized, multicenter clinical studies in adults **(Study 1 and 2)**
- A total of 905 patients (Study 1) and 870 patients (Study 2) were randomized to either placebo or Trulance 3mg once daily

Clinical Trials

- Eligible patients had to meet modified Rome III criteria for ≥3 months prior to the screening visit with symptom onset for ≥6 months prior to diagnosis
- Patients also had to report ≥2 of the following:
  - Straining during ≥25% of defecations
  - Lumpy or hard stool in ≥25% of defecations
  - Sensation of incomplete evacuations for ≥25% of defecations
  - Sensation of anorectal obstruction/blockage for ≥25% of defecations

Clinical Trials

- The **efficacy of Trulance** was assessed using a responder analysis and change-from-baseline in complete spontaneous bowel movement (CSBM) and SBM endpoints

- Efficacy was assessed using information provided by patients on a daily basis in an electronic diary

Clinical Trials

- A **responder** was defined as a patient who had ≥3 CSBMs in a given week and an increase of ≥1 CSBM from baseline in the same week for ≥9 weeks out of the 12 week treatment period and ≥3 of the last 4 weeks of the study

Clinical Trials

- In Study 1, **21%** of Trulance-treated patients were responders vs. **10%** of placebo-treated patients
  - Treatment difference 11% (95% CI: 6.1%, 15.4%)
- In Study 2, **21%** of Trulance-treated patients were responders vs. **13%** of placebo-treated patients
  - Treatment difference 8% (95% CI: 2.6%, 12.4%)

Clinical Trials

- Over the 12-week treatment period, improvements were seen in stool frequency (number of CSBMs/week and SBMs/week) and/or stool consistency, and/or in the amount of straining with bowel movements in the Trulance group vs. placebo group

- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  http://www.empr.com/trulance/drug/34675/