

Trulance® Start Form and Prescriptions

Fax 1-844-627-3827 Phone 1-844-796-3757

SYNERGY
PHARMACEUTICALS

Trulance®
(plecanatide)

1. Patient Information

Please complete all fields to prevent any delays.

First Name Last Name SS# (Last four only)

Male Female

Sex Date of Birth (MM/DD/YYYY)

Address

City State Zip

Cell Phone Home Phone E-mail Address

Preferred Method of Contact: Cell Phone Home Phone Email

Preferred Time of Contact: Morning Afternoon Evening

Ok to leave a message: Yes No

The undersigned patient hereby represents and warrants that:

I hereby authorize Trulance Access Services and/or contractors to communicate with me via the email address provided for the purpose of providing me with information pertaining to my coverage for Trulance®

2. Insurance Information

Please include copies of both sides of all insurance plan cards.

Primary Insurance Phone #

Policy Holder Name Relationship to Patient

Insurance ID # Group #

BIN # PCN #

Secondary Insurance Phone #

Policy Holder Name Relationship to Patient

Insurance ID # Group #

BIN # PCN #

Prescription Drug Coverage Phone # ID#

X

Patient/Legal Guardian Signature

/ /

Date of Signature (MM/DD/YYYY)

The undersigned patient hereby represents and warrants that:

I hereby authorize my Healthcare Providers office to provide Trulance Access Services and/or contractors with my private personal information including protected health information as defined in the Health Insurance Portability and Accountability Act of 1996 (HIPAA). I also authorize Trulance Access Services and/or contractors to maintain and use this information including my name, DOB, social security number, diagnosis, insurance information or other relevant information in order to conduct benefit verifications, insurance research, and coverage appeals on my behalf.

3. Prescriber Information

First Name Last Name

Phone Fax

Practice Name Office Contact

Preferred Time of Contact Tax ID #

Address

Medicaid Provider # Medicare Provider #

City State Zip

State Medical License # NPI #

4. Starter Dose Dispense

Dispense: Trulance® (plecanatide) 3 mg, quantity 30

Directions: Take one tablet orally once daily

Prescriber Signature: _____ Date: _____

Has a Prior Authorization been denied and appeal submitted to insurance? Yes No

Does physician's office have a No Sampling policy? Yes No

ICD-10 Code: K59.04 Chronic Idiopathic Constipation (CIC) K58.1 Irritable Bowel Syndrome with Constipation (IBS-C)

The undersigned, as treating physician, represents and warrants that;

- (i) This prescription is medically appropriate for this patient and I will be supervising this patient's treatments.
- (ii) I understand that any medication to be provided to this patient by Synergy through any of the patient assistance programs is complimentary, provided at no cost and may not be resold or billed to third-party payers, returned for credit or otherwise be placed in the stream of commerce.
- (iii) I certify and warrant that all information supplied to Trulance Access Services, contractors, and subcontractors in connection with this enrollment form is accurate and has been obtained pursuant to an appropriate and valid patient authorization allowing for the release, transfer and use of such information by Synergy or its agents, contractors or subcontractors in accordance with State and Federal law for verification and/or preauthorization of patient's benefits.

X

Prescriber Signature

/ /

Date of Signature (MM/DD/YYYY)

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.

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 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.

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 also see the [full Prescribing Information](#), including Box Warning, for additional risk information at www.Trulance.com.

References: 1. Trulance [package insert]. New York, NY: Synergy Pharmaceuticals Inc.