Motegrity (prucalopride)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Motegrity
- **Generic name:** Prucalopride
- **Pharmacological class:** Selective 5-HT_4 receptor agonist
- **Strength and Formulation:** 1mg, 2mg; tabs
- **Manufacturer:** Shire US, Inc.
- **How supplied:** Tabs—30
- **Legal Classification:** Rx

Motegrity


Rx Only
NDC 54092-547-03
motegrity™
(prucalopride) tablets
2 mg
Usual Dose: One tablet once daily.
30 Tablets
PRU
2

Indication

- Chronic idiopathic constipation (CIC) in adults

Dosage & Administration

- **≥17yrs:** 2mg once daily
- **Severe renal impairment (**CrCl <30mL/min): 1mg once daily

Considerations for Special Populations

- **Pregnancy:** Insufficient data to identify any drug-associated risks
- **Nursing mothers:** Consider benefits of breastfeeding and any potential adverse effects on child
- **Pediatric:** <17yrs: not established
- **Elderly:** Adjust dose based on renal function
- **Renal impairment:** ESRD requiring dialysis: not recommended

Contraindications

- Intestinal **perforation** or **obstruction** due to structural or functional disorder of the gut wall, obstructive ileus, or severe inflammatory conditions of the intestinal tract (eg, Crohn disease, ulcerative colitis, toxic megacolon/megarectum)

Warnings/Precautions

- Monitor for worsening **depression** or emergence of **suicidal thoughts** and **behaviors**; discontinue if occurs

Adverse Reactions

- Headache
- Abdominal pain
- Nausea
- Diarrhea
- Abdominal distention
- Dizziness
- Vomiting
- Flatulence
- Fatigue
- Suicidal ideation/behavior

Mechanism of Action

- Prucalopride, a selective serotonin type 4 (5-HT4) receptor agonist, is a **gastrointestinal (GI) prokinetic agent** that stimulates colonic peristalsis (high-amplitude propagating contractions [HAPCs]), which increases bowel motility

Clinical Studies

- Motegrity was evaluated in 6 double-blind, placebo-controlled, randomized, multicenter trials (N=2484) in adults with CIC
  - **Studies 1 through 5:** 12-week treatment duration
  - **Study 6:** 24-week treatment duration

Clinical Studies

- Eligible patients had a history of chronic constipation defined as <3 spontaneous bowel movements (SBMs) per week that resulted in a feeling of complete evacuation and 1 or more of the following symptoms for >25% of bowel movements in the past 3 months, with symptoms onset >6 months prior to screening:
  - Lumpy or hard stools
  - Sensation of incomplete evacuation
  - Straining at defecation

Clinical Studies

- For the **primary efficacy endpoint**, a responder was defined as a patient with an average of 3 or more complete SBMs (CSBMs) per week, over the 12-week treatment period

Clinical Studies

- Efficacy responder rates for Motegrity vs placebo:
  - Study 1: 33% vs 10% (difference 23%; *P* <.001)
  - Study 2: 38% vs 18% (difference 20%; *P* <.001)
  - Study 3: 19% vs 10% (difference 10%; *P* =.002)
  - Study 4: 29% vs 13% (difference 16%; *P* <.001)
  - Study 5: 24% vs 12% (difference 12%; *P* <.001)
  - Study 6: 25% vs 20% (difference 5%; *P* =.341)

Clinical Studies

- In all studies, improvement in the **frequency of CSBMs per week** was seen as early as week 1 and was maintained through week 12

- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

https://www.empr.com/drug/motegrity/