Motegrity (prucalopride)

NEW PRODUCT SLIDESHOW

MPR
Introduction

- **Brand name:** Motegrity
- **Generic name:** Prucalopride
- **Pharmacological class:** Selective 5-HT\textsubscript{4} receptor agonist
- **Strength and Formulation:** 1mg, 2mg; tabs
- **Manufacturer:** Shire US, Inc.
- **How supplied:** Tabs—30
- **Legal Classification:** Rx
Motegrity
Indication

- Chronic idiopathic constipation (CIC) in adults
Dosage & Administration

- \( \geq 17\text{yrs} \): 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 (e.g., 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.
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
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
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%; \( P = .341 \))
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/motegriti/