

Motegrity™ (prucalopride) – New drug approval

- On December 17, 2018, [Shire announced](#) the FDA approval of [Motegrity \(prucalopride\)](#), for the treatment of chronic idiopathic constipation (CIC) in adults.
- CIC is a common condition affecting roughly 14% of the adult population. Symptoms can range from straining and bloating, to infrequent, or incomplete bowel movements. It is believed that CIC may be caused by insufficient movement of the colon muscle.
- Motegrity, a selective serotonin type (5-HT₄) receptor agonist, is a gastrointestinal prokinetic agent that stimulates colonic peristalsis (contractions), which increases bowel motility.
- The efficacy of Motegrity for the treatment of CIC was evaluated in six placebo-controlled studies in 2,484 adult patients. Studies 1 through 5 were 12-weeks and study 6 was 24 weeks. The primary efficacy endpoint was defined as a patient with an average of 3 or more complete, spontaneous bowel movements per week, over the 12-week treatment period.

Study	Efficacy Responder Rates		Treatment Difference (95% CI)	p value
	Motegrity	Placebo		
Study 1	33%	10%	23 (16, 30)	p < 0.001
Study 2	38%	18%	20 (11, 29)	p < 0.001
Study 3	19%	10%	10 (4, 16)	p = 0.002
Study 4	29%	13%	16 (8, 24)	p < 0.001
Study 5	24%	12%	12 (4, 19)	p < 0.001
Study 6	25%	20%	5 (-4, 14)	p = 0.341

- Motegrity is contraindicated in patients with hypersensitivity to Motegrity and in patients with intestinal perforation or obstruction due to structural or functional disorder of the gut wall, obstructive ileus, and severe inflammatory conditions of the intestinal tract such as Crohn's disease, ulcerative colitis, and toxic megacolon/megarectum.
- A warning and precaution of Motegrity includes suicidal ideation and behavior.
- The most common adverse reactions (≥ 2%) with Motegrity use are headache, abdominal pain, nausea, diarrhea, abdominal distension, dizziness, vomiting, flatulence, and fatigue.
- The recommend dose of Motegrity is 2 mg orally once daily, with or without food.
- Shire plans to launch Motegrity in 2019. Motegrity will be available as 1 mg and 2 mg tablets.