WITH MOTEGRITY, IT'S POSSIBLE TO TAKE ADULT CHRONIC IDIOPATHIC CONSTIPATION (CIC) PATIENTS FROM

STASIS TO *PERISTALSIS*

Stimulated colonic peristalsis is possible with Motegrity, the only FDA-approved *selective* serotonin type 4 (5-HT_4) receptor agonist for adults with CIC.[1-4]

IMPORTANT SAFETY INFORMATION

Contraindications

- Hypersensitivity to Motegrity. Reactions including dyspnea, rash, pruritus, urticaria, and facial edema have been observed
- Intestinal perforation or obstruction due to structural or functional disorder of the gut wall, obstructive ileus, severe inflammatory conditions of the intestinal tract such as Crohn's disease, ulcerative colitis, and toxic megacolon/megarectum

Please see additional Important Safety Information throughout and click for full Prescribing Information.

motegrity®
(prucalopride) tablets 1mg, 2mg

Are your CIC patients looking for a different treatment approach?

If you have a patient with Chronic Idiopathic Constipation (CIC) who is looking for something different, it may be a sign that their current approach may not be working for them.

Have your patients:

- ☐ Expressed frustration with recurring symptoms?
- ☐ Had less than 3 complete spontaneous bowel movements per week?
- ☐ Felt a sense of incomplete evacuation?
- ☐ Asked about dosing frequency?
- ☐ Stopped taking their CIC medication as prescribed?

Colonic dysmotility could be a factor affecting your CIC patients[5]

Consider a prokinetic approach for patients looking for a treatment that works differently

Unlike other prescription CIC treatments, Motegrity works differently by stimulating natural movements of the colon muscle (peristalsis)[1,6-8]

HERE'S HOW

1 | Absorb

One 2 mg oral dose of Motegrity in healthy participants reached peak plasma concentrations within 2–3 hours[1]

See median time-to-first bowel movement on page 11.

2 | Activate

In the colon, Motegrity **selectively binds** and **activates 5-HT_4 receptors**[1,8,10]

Motegrity showed no cross-reactivity with 5-HT_{2A}, 5-HT_{2B}, 5-HT_3, motilin, or CCK-A receptors in *in vitro* studies at concentrations exceeding 5-HT_4 receptor affinity by 150-fold or greater.[1,9]

3 | Release

Colonic 5-HT_4 receptor activation facilitates the release of acetylcholine as seen in *in vitro* studies[1,8,10]

4 | Move

Colonic peristalsis is stimulated, increasing bowel motility[1,8,10]

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Suicidal Ideation and Behavior: In clinical trials, suicides, suicide attempts and suicidal ideation have been reported. Postmarketing cases of suicidal ideation and behavior as well as self-injurious ideation and new onset or worsening of depression have been reported within the first few weeks of starting Motegrity. A causal association between treatment with Motegrity and an increased risk of suicidal ideation and behavior has not been established. Monitor patients for new onset or worsening of depression and emergence of suicidal thoughts and behavior. Instruct patients to discontinue Motegrity immediately and contact their healthcare provider if they experience any of these symptoms.

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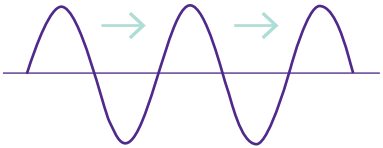
Target the muscle behind colonic motility

A different class of CIC treatment

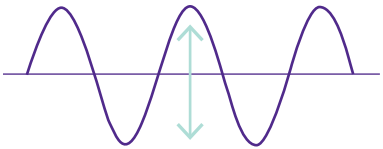
Motegrity is the only FDA-approved selective serotonin type 4 (5-HT_4) receptor agonist for adults with CIC. It functions as a GI prokinetic that stimulates colonic peristalsis (i.e. HAPCs), which increases bowel motility.[1,6-8]

In a pharmacodynamic CIC study:



More frequent HAPCs

A single 2 mg dose of Motegrity increased HAPC frequency during the first 12 hours compared to osmotic laxatives[1]



Increased HAPC amplitude

Motegrity 4 mg* once daily for 7 days increased HAPC amplitude in healthy participants compared to placebo without affecting colonic phasic activity[1]

*Twice the max recommended dose of 2 mg.

IMPORTANT SAFETY INFORMATION

Adverse Reactions

Most common adverse reactions (≥2%) are headache, abdominal pain, nausea, diarrhea, abdominal distension, dizziness, vomiting, flatulence, and fatigue.

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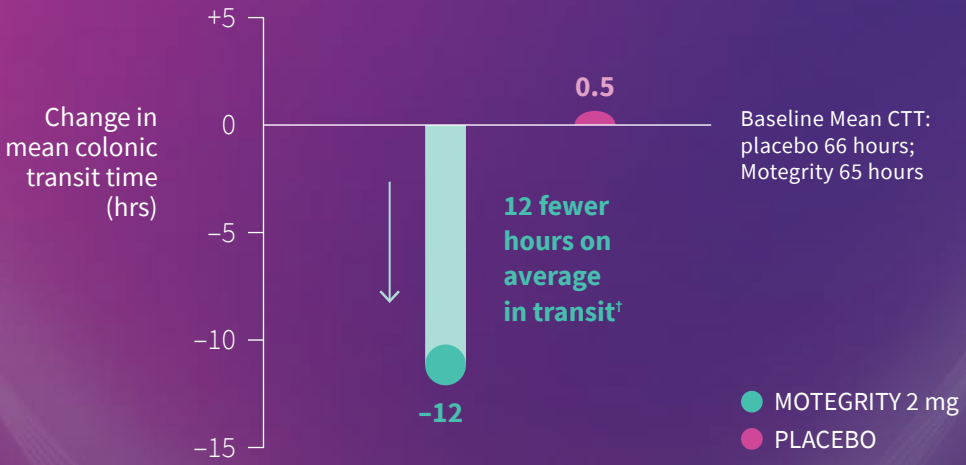
Accelerate colonic transit time (CTT) in adults with CIC*[1]

Motegrity 2 mg reduced mean CTT by 12 hours vs. baseline†



*Results from an integrated analysis of 3 randomized, placebo-controlled, dose-finding trials in adults (n=280) with CIC. Mean change in CTT was −12 hours (from a baseline=65 hrs) with Motegrity 2 mg group vs. +0.5 hrs (baseline=66 hrs) in the placebo group.

†*P*<0.001 vs baseline.

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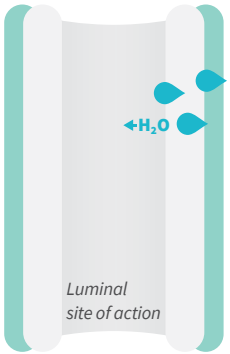
Treatment mechanisms in the management of CIC

Osmotic laxatives

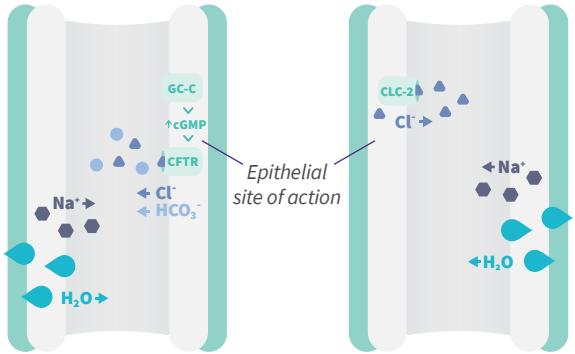


Create an osmotic gradient that draws water into the intestinal lumen.[6,11,12]

Prosecretory agents

GC-C agonist

CLC-2 agonist

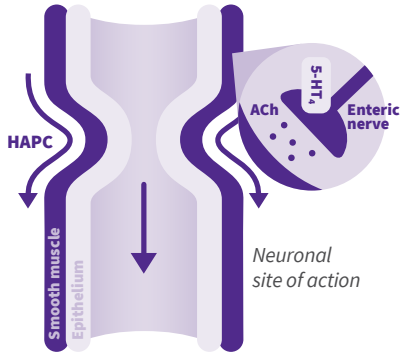


Activate GC-C receptors, leading to increased secretion of Cl^- and HCO_3^-, followed by Na^+ and water.[6,11,13,14]

Activate CLC-2 channels, increasing Cl^- secretion, followed by Na^+ and water.[6,11,14]

Serotonergic agents

5-HT_4 receptor agonist



Activate 5-HT_4 receptors, promoting ACh release, colonic smooth muscle contractions and peristalsis.[1,6,8,10]

Overview of treatment mechanism is not a comparison of treatment safety or efficacy. These are not all the current treatments or rescue medications for adults with CIC.

The above are illustrations of colons. The diagrams are a simplified representation of the purported primary MOA.

ACh=acetylcholine; CFTR=cystic fibrosis transmembrane conductance regulator; cGMP=cyclic guanosine monophosphate; CLC-2=chloride channel-type 2; GC-C=guanylate cyclase-C; HAPC=high amplitude propagating contraction

Please see additional Important Safety Information throughout and click for full Prescribing Information.

Efficacy evaluated in 6 clinical trials with 2484 patients[1]

TREATMENT DURATION[1]

Studies 1–5: 12 weeks

Study 6: 24 weeks

Description

The efficacy of once-daily Motegrity ≤2 mg was evaluated in six double-blind, placebo-controlled, randomized, multicenter clinical trials.[1]

Patient population

2484 adult patients with CIC (Intent-to-Treat population: Motegrity ≤2 mg [n=1237], placebo [n=1247]). Overall, most patients were female (76%) and Caucasian (76%), with a mean age of 47 ± 16 years (range 17 to 95).[1]

Primary efficacy endpoint (responders)

Responders were defined as proportion (%) of patients with an average of ≥3 complete spontaneous bowel movements (CSBMs) per week, over the 12-week treatment period, considered a normalization of bowel movement frequency. Efficacy was assessed based on patients' daily diaries.[1]

IMPORTANT SAFETY INFORMATION

Use in Specific Populations

- **Lactation:** Motegrity is present in breast milk. Consider risks and benefits of breastfeeding
- **Pediatric:** Safety and effectiveness in pediatric patients have not been established
- **Renal Impairment:** A decreased dosage is recommended in patients with severe renal impairment. Avoid Motegrity in patients with end-stage renal disease requiring dialysis

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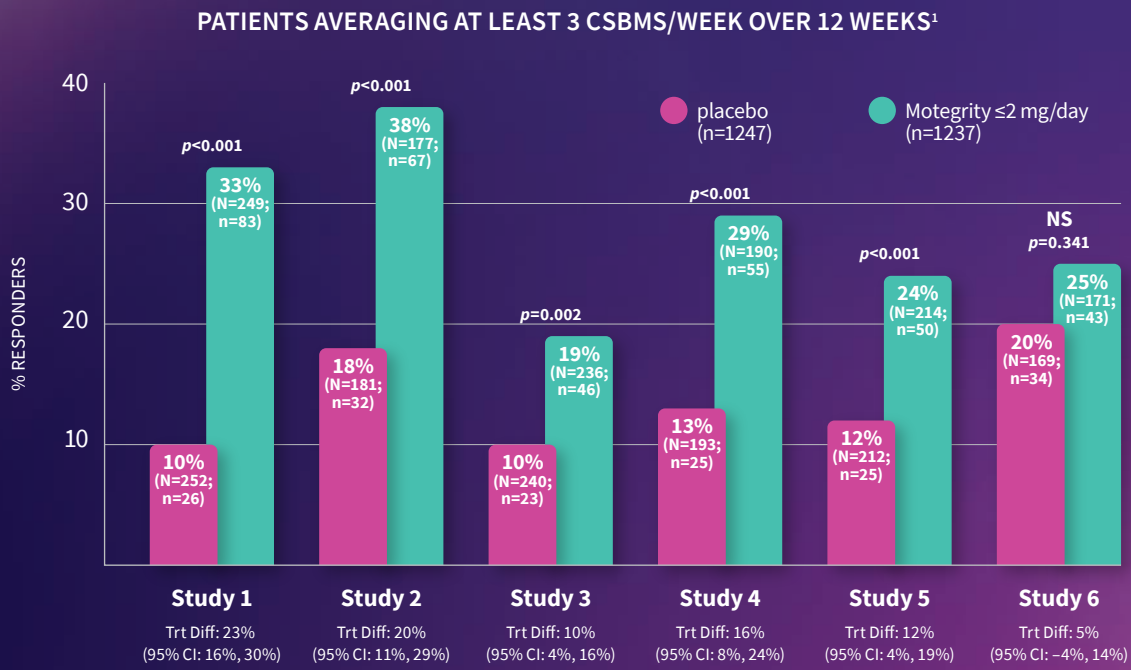
For adults with Chronic Idiopathic Constipation (CIC)

Effect on normalization of CSBM frequency



Motegrity was shown to help normalize complete spontaneous bowel movement frequency (avg. ≥3 CSBMs/week over 12 weeks) across 5/6 trials[1]

p-values based on a Cochran-Mantel-Haenszel test.
Trt Diff=treatment difference; N=patients per group; n=responders; NS=not significant

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For adults with Chronic Idiopathic Constipation (CIC)

ACROSS ALL 6 STUDIES

Motegrity demonstrated sustained effect over 12 weeks[1]

A rapid response with Motegrity was seen as early as week 1, with improvements maintained through 12 weeks of treatment.[1]

RESULTS SEEN:

As early as
Week 1

→

Sustained through
Week 12

IMPORTANT SAFETY INFORMATION

Contraindications

- Hypersensitivity to Motegrity. Reactions including dyspnea, rash, pruritus, urticaria, and facial edema have been observed
- Intestinal perforation or obstruction due to structural or functional disorder of the gut wall, obstructive ileus, severe inflammatory conditions of the intestinal tract such as Crohn's disease, ulcerative colitis, and toxic megacolon/megarectum

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For adults with Chronic Idiopathic Constipation (CIC)

ACROSS ALL 6 STUDIES

Median time-to-first CSBM and SBM reduced with Motegrity vs. placebo[1]

7–15 days faster
median time-to-first CSBM[1]

Patients taking Motegrity had their first CSBM 1.4 to 4.7 days into treatment vs. 9.1 to 20.6 days for those taking placebo (ranges are median values from 6 studies)[1]

2.5x faster
median time-to-first SBM[1]

Patients taking Motegrity had their first SBM 0.1 to 0.4 days into treatment vs. 1 to 1.6 days for those taking placebo (ranges are median values from 6 studies)[1]

CSBM=complete spontaneous bowel movement; SBM=spontaneous bowel movement

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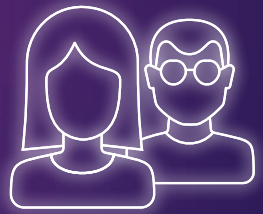
For adults with Chronic Idiopathic Constipation (CIC)

Alternative efficacy endpoint

Motegrity was also evaluated using a more rigorous endpoint in a post-hoc analysis[1]

In an alternative efficacy endpoint analysis, a responder was defined as a patient who had at least 3 CSBMs and an increase of at least 1 CSBM from baseline in a given week for at least 9 weeks out of the 12-week treatment period and for at least 3 of the last 4 weeks of the treatment period.[1]

Study	Motegrity 1 or 2 mg once daily N	Motegrity 1 or 2 mg once daily n (%)	placebo N	placebo n (%)	Treatment Difference (95% CI)
Study 1	249	65 (26)	252	22 (9)	17 (11, 24)
Study 2	177	57 (32)	181	25 (14)	18 (10, 27)
Study 3	236	30 (13)	240	13 (5)	8 (2, 12)
Study 4	190	37 (19)	193	15 (8)	11 (5, 18)
Study 5	214	34 (16)	212	11 (5)	11 (5, 16)
Study 6	171	29 (17)	169	22 (13)	4 (-4, 12)



ADDITIONAL ENDPOINT

Nearly half of Motegrity patients saw improvement in weekly CSBM frequency

In an additional endpoint analysis, a greater % of patients taking Motegrity had a mean increase of ≥1 CSBM/week vs. placebo over the 12-week treatment period (47.0% vs. 29.9%)[1]

IMPORTANT SAFETY INFORMATION

Adverse Reactions

Most common adverse reactions (≥2%) are headache, abdominal pain, nausea, diarrhea, abdominal distension, dizziness, vomiting, flatulence, and fatigue.

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Safety profile studied in 2530 adult and elderly patients with CIC[1]

The safety and tolerability profile of Motegrity was studied in 2530 patients (Motegrity 2 mg once daily [n=1251], placebo [n=1279]) with CIC across 6 double-blind, placebo-controlled clinical trials of 12 to 24 weeks duration. Overall, most patients were female (76%) and Caucasian (76%), with a mean age of 47 years (range 17 to 95).[1]

Suicidal Ideation and Behavior: In clinical trials, suicides, suicide attempts and suicidal ideation have been reported. Postmarketing cases of suicidal ideation and behavior as well as self-injurious ideation and new onset or worsening of depression have been reported within the first few weeks of starting Motegrity. A causal association between treatment with Motegrity and an increased risk of suicidal ideation and behavior has not been established. Monitor patients for new onset or worsening of depression and emergence of suicidal thoughts and behavior. Instruct patients to discontinue Motegrity immediately and contact their healthcare provider if they experience any of these symptoms.[1]

No overall differences in safety and effectiveness were observed between elderly and younger patients. Adjust the dosage in elderly patients based on renal function. Avoid Motegrity in patients with end-stage renal disease requiring dialysis.[1]

ADDITIONAL DETAILS

In the double-blind trials:

- One patient reported a suicide attempt 7 days after the end of treatment with Motegrity 2 mg once daily; none were reported in patients on placebo

In the open-label trials:

- Two patients reported a suicide attempt and another patient reported suicidal ideation
- Completed suicide was reported in two patients, previously treated with Motegrity 2 mg or 4 mg; both discontinued Motegrity for at least one month prior to the event

Please see additional Important Safety Information throughout and click for full Prescribing Information.

Common adverse reactions* reported in patients receiving Motegrity 2 mg or placebo[1]

RESULTS FROM DOUBLE-BLIND, PLACEBO-CONTROLLED TRIALS OF AT LEAST 12 WEEKS' DURATION

Adverse Reaction	Motegrity 2 mg once daily (N=1251†)	placebo (N=1279)
Headache	19%	9%
Abdominal Pain‡	16%	11%
Nausea	14%	7%
Diarrhea	13%	5%
Abdominal Distension	5%	4%
Dizziness	4%	2%
Vomiting	3%	2%
Flatulence	3%	2%
Fatigue	2%	1%

*Reported in ≥2% of patients receiving Motegrity and a rate higher than patients receiving placebo.
†Includes 93 patients who started on Motegrity 1 mg and increased to Motegrity 2 mg.
‡Includes abdominal pain, upper abdominal pain, lower abdominal pain, abdominal tenderness, abdominal discomfort, and epigastric discomfort.

Less common adverse reactions reported in <2% of patients receiving Motegrity 2 mg once daily included: abnormal GI sounds, decreased appetite, migraine and pollakiuria.

Additional Safety and Tolerability

Diarrhea or headache adverse events typically resolved within a few days if reported within the first week of treatment[1]

The majority of patients who reported diarrhea did so in the first week of treatment (n=110/157), and the majority who reported headache did so in the first two days of treatment (n=157/237). For these patients, symptoms typically resolved within a few days (n=80/110 for diarrhea; n=102/157 for headache).[1]

IMPORTANT SAFETY INFORMATION

Use in Specific Populations

- **Lactation:** Motegrity is present in breast milk. Consider risks and benefits of breastfeeding
- **Pediatric:** Safety and effectiveness in pediatric patients have not been established
- **Renal Impairment:** A decreased dosage is recommended in patients with severe renal impairment. Avoid Motegrity in patients with end-stage renal disease requiring dialysis

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Severe diarrhea was reported in 1.8% of patients treated with Motegrity 2 mg compared to 1% of patients in the placebo group, and had a similar onset and duration as diarrhea overall.[1]

Overall, discontinuation due to adverse events was low at 5% with Motegrity 2 mg once daily and 3% with placebo[1]

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Cardiovascular Safety Analysis

The cardiovascular safety of Motegrity was evaluated in a MACE analysis of double-blind, placebo-controlled and open-label studies, as well as in a retrospective observational study that demonstrated no increase in the risk of MACE with Motegrity relative to polyethylene glycol (PEG).[1]

Major Adverse Cardiovascular Events (MACE) were defined as: cardiovascular death, nonfatal myocardial infarction, and nonfatal stroke[1]

28 completed clinical trials providing safety data for Motegrity[1]

19 double-blind and 9 open-label studies were completed for the evaluation of AEs of special interest

565 patient-years of exposure for Motegrity in double-blind trials[1]

The total exposure in the double-blind trials was 565 patient-years in the Motegrity group, 384 patient-years in the placebo group, and 2769 patient-years in the double-blind and open-label clinical trials

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FOR ADULTS WITH CHRONIC IDIOPATHIC CONSTIPATION (CIC)

Once daily. Anytime. With or without food.[1]

Motegrity offers simple dosing to work with your patients' schedule.[1]

Once-daily dosing

Any time of the day

With or without food

IMPORTANT SAFETY INFORMATION

Contraindications

- Hypersensitivity to Motegrity. Reactions including dyspnea, rash, pruritus, urticaria, and facial edema have been observed
- Intestinal perforation or obstruction due to structural or functional disorder of the gut wall, obstructive ileus, severe inflammatory conditions of the intestinal tract such as Crohn's disease, ulcerative colitis, and toxic megacolon/megarectum

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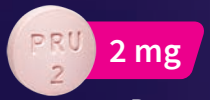
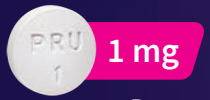
Two dosage strengths

It is important for patients to understand that Motegrity must be taken once daily as prescribed. Advise patients to store Motegrity in the original container to protect from moisture.[1]



2 mg

- Recommended once-daily adult CIC dosage[1]



1 mg

- Recommended once daily-dosage for CIC patients with severe renal impairment (creatinine clearance <30 mL/min)[1]
- Avoid Motegrity in patients with end-stage renal disease requiring dialysis[1]

Tablets not actual size

Please see additional Important Safety Information throughout and click for full Prescribing Information.

The Motegrity Savings Card gives eligible patients options to save on their prescription

90 DAY

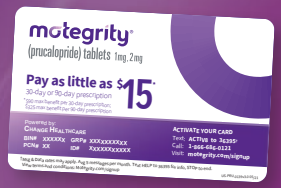
Maximize Savings*

to maintain their momentum

A 90-day prescription costs the same as a 30-day

*Appropriate, eligible, commercially insured patients pay the same for either a 30- or 90-day prescription

Pay as little as $15 for 90 days of Motegrity†



†Up to $325 max benefit per use per 90-day prescription; $90 max benefit per use per 30-day prescription.
See Terms and Conditions below.

Motegrity Savings Card Terms & Conditions

Eligible Commercially Insured patients may pay as little as $15 and receive up to $90 off their co-pay or out of pocket expenses per 30 day supply of Motegrity® (prucalopride). Offer is tiered based on quantity dispensed: Tier 1: 1-30 tablets; Patient pays $15, up to max $90 benefit for 1 use ($2700 lifetime); Tier 2: 31-60 tablets; Patient pays $15, up to max $180 benefit for 2 use(s) ($2700 lifetime); Tier 3: 61-90 tablets; Patient pays $15, up to max $325 benefit for 3 use(s) ($3250 lifetime). Offer valid for up to 30 uses through offer expiry. A valid Prescriber ID# is required on the prescription. Offer valid for patients ages 18 and older. Offer not valid for cash paying patients.

Restrictions: This offer is valid in the United States, Puerto Rico, and the U.S. Territories. Offer not valid for prescriptions reimbursed under Medicaid, a Medicare drug benefit plan, Tricare, or other federal or state health programs (including any state medical assistance program) or where prohibited by the health insurance provider. Cash Discount Cards and other non-insurance plans are not valid as primary under this offer. If the patient is eligible for drug benefits under any such program, the patient cannot use this offer. By using this offer, the patient certifies that he or she will comply with any terms of his or her health insurance contract requiring notification to his or her payor of the existence and/or value of this offer. Offer not valid for patients under 18 years of age. It is illegal to (or offer to) sell, purchase, or trade this offer. This offer is not transferable and is limited to one offer per person and may not be combined with any other coupon, discount, prescription savings card, rebate, free trial, patient assistance, or other offer. Not valid if reproduced. Void where prohibited by law. Program managed by ConnectiveRx on behalf of Takeda Pharmaceuticals U.S.A., Inc. The parties reserve the right to discontinue, rescind, revoke or amend this offer without notice at any time. This is not health insurance.

Motegrity is here to cover your adult patients

Mobile Savings Card

Patients can now add their Motegrity Savings Card to the Mobile Wallet on their phone and use it at the pharmacy. Simply text SAVE2DAY to 36395* to activate the card and receive refill reminders via text

*Message & data rates may apply. Average 5 messages per month. Text HELP to 36395 for info, STOP to end. View Terms and Conditions: Motegrity.com/signup

Insurance access

Expanded access for patients with coverage on plans nationwide†
Check local coverage at MotegrityCoverage.com

†Takeda does not guarantee coverage or reimbursement for Motegrity. Check individual patients' coverage as formulary status is subject to change.

Request samples

Interested in Motegrity samples? Visit MySampleCloset.com/Takeda for more information

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INDICATION

Motegrity (prucalopride) is a serotonin-4 (5-HT_4) receptor agonist indicated for the treatment of chronic idiopathic constipation (CIC) in adults.

Please see additional Important Safety Information throughout and click for full Prescribing Information.

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References:

1. Motegrity (prucalopride) Prescribing Information. Lexington, MA: Takeda Pharmaceuticals America, Inc. **2.** Emmanuel A, Cools M, Vandeplassche L, et al. *Am J Gastroenterol*. 2014;109(6):887-894. **3.** Miner PB, Camilleri M, Burton D, et al. *Neurogastroenterol Motil*. 2016;28(9):1341-1348. **4.** Enterostasis. Stedman's Online. https://stedmansonline.com/content.aspx?term=ENTEROSTASIS. Accessed [December 2, 2022]. **5.** Dinning P, Di Lorenzo C. *Best Pract Res Clin Gastroenterol*. 2011;25:89-10. **6.** Camilleri M, Ford AC, Mawe GM, et al. *Nat Rev Dis Primers*. 2017;3:17095. **7.** Tack J, Camilleri M, Chang L, et al. *Aliment Pharmacol Ther*. 2012;35(7):745-767. **8.** Mawe GM, Hoffman JM. *Nat Rev Gastroenterol Hepatol*. 2013;10(8):473-486. **9.** Briejer MR, Bosmans JP, Van Daele P, et al. *Eur J Pharmacol*. 2001;423(1):71-83. **10.** Gershon MD, Tack *J.Gastroenterology*. 2007;132(1):397-414. **11.** Lacy B, Hussain Z, Mearin F. *Neurogastroenterol Motil*. 2014;26(6):749-763. **12.** Izzy M, Malieckal A, Little E, et al. *World J Gastrointest Pharmacol Ther*. 2016;7(2):334-342. **13.** Lacy BE, Levenick JM, Crowell M. T*herap Adv Gastroenterol*. 2012;5(4):233-247. **14.** Menees S, Saad R, Chey WD. *Nat Rev Gastroenterol Hepatol*. 2012;9(11):661-674.

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Go prokinetic with Motegrity

ICD-10 CODE FOR CIC: K59.04[14]

- **A different class of treatment that works by stimulating colonic peristalsis to increase bowel motility.[1,6-8]**
- **Motegrity was shown to help normalize CSBM frequency (avg. ≥3 CSBMs/week over 12 weeks) across 5 of 6 trials.[1]**
- **A rapid response was seen as early as week 1, with improvements maintained throughout 12 weeks of treatment.[1]**

The efficacy of Motegrity ≤2 mg was evaluated in six double-blind, placebo-controlled, randomized, multicenter clinical trials lasting 12 weeks (Studies 1–5) and 24 weeks (Study 6) in adult patients with CIC (N=2484). Overall, most patients were female (76%) and Caucasian (76%), with a mean age of 47 ± 16 years.[1]
See clinical trial results on page 8.

INDICATION

Motegrity® (prucalopride) is a serotonin-4 (5-HT_4) receptor agonist indicated for the treatment of chronic idiopathic constipation (CIC) in adults.

IMPORTANT SAFETY INFORMATION

Adverse Reactions

Most common adverse reactions (≥2%) are headache, abdominal pain, nausea, diarrhea, abdominal distension, dizziness, vomiting, flatulence, and fatigue.

Please see additional Important Safety Information throughout and click for full Prescribing Information.

Improve the chances that your patients will get coverage with PARx Prior Authorization Support System (PASS)®*

- PARx PASS® uses an online portal that allows prescribers to manage PA requests for their patients' medications
- Input the required information through a simple form and let PARx take care of the rest
- The HIPAA-compliant portal is easy to navigate and uses a universal PA format for all plans

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*PARx is not a Takeda-owned program. It is a free, web-based, third-party system that may help to streamline the prior authorization process.

motegrityhcp.com

Takeda

motegrity® (prucalopride) tablets 1mg, 2mg