Patients treated with GIMOTI had significantly reduced healthcare resource utilization

Gimoti® (metoclopramide) nasal spray

Compared to patients treated with oral metoclopramide

Diabetic gastroparesis (DGP) can cause severe complications that impact quality of life and require increased levels of care. Multiple studies have evaluated the substantial healthcare burden patients with gastroparesis experience.

Patients with DGP have **2x to 3x higher healthcare costs** than patients with diabetes alone due to significantly more hospital and physician office visits.[1]

DGP patients were **hospitalized 4x a year, on average,** often due to nausea, vomiting, and dehydration.[2]

Among gastrointestinal disorders, **gastroparesis accounts for the highest 30-day hospital readmission rate.**[3]

Patients treated with GIMOTI had significantly fewer inpatient and emergency department visits over 6 months compared to patients treated with oral metoclopramide[4,5]

↓68%
P=0.005

↓60%
P=0.007

These visits were for nausea, vomiting, and DGP.*†

Patients treated with GIMOTI also had 36% fewer visits to a physician's office compared to patients treated with oral metoclopramide (174 and 273, respectively).

Oral metoclopramide (n=257) GIMOTI (n=257)

61.5% of patients treated with GIMOTI had previously taken oral metoclopramide.[4]

Study design[4]:

A retrospective real-world healthcare resource utilization (HRU) study in DGP patients (N=514) who were treated with oral metoclopramide or GIMOTI. Frequency of healthcare visits was assessed over a 6-month period. Patients were ≥18 years of age.

Demographics[4]:

Both groups: average age of 53 years, 77% female, average Charlson Comorbidity Index (CCI) Score‡ 2.2, and DGP severity§ of 31%

Data presented in this piece are from retrospective cohort studies, and selection bias may limit the external validity of the results. Observed results may be due to unobserved factors associated with treatment and outcome.

*6 months following the index therapy.[4]

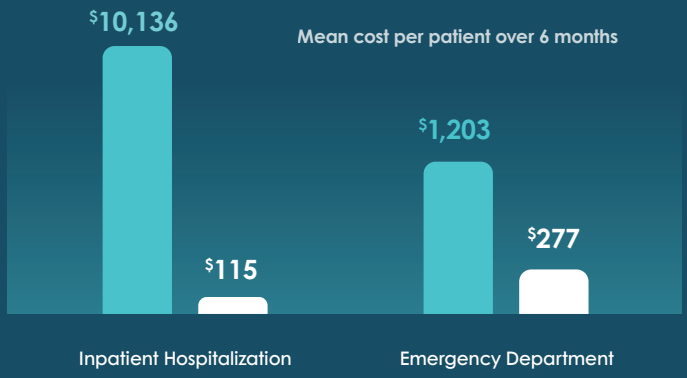
†Nausea, vomiting, and gastroparesis-related HRU were assessed by examining only insurance claims with ICD-10 diagnosis codes specific to each condition.[4]

‡CCI predicts the risk of patient mortality associated with comorbidities; 2.2 indicates low risk.[6]

§DGP severity was defined as having experienced emergency department or inpatient hospitalization in the 6 months pre-index.[4]

Please see accompanying full Prescribing Information, including Boxed Warning and Medication Guide, located in the inside pocket.

Patients treated with GIMOTI had significantly lower healthcare costs over 6 months compared to patients treated with oral metoclopramide[7]



Lower costs were also seen in:

- Outpatient hospital visits
- Lab/home/telehealth visits
- Office/clinic visits

Pharmacy costs within the GIMOTI group were higher than the oral metoclopramide group, but were not statistically significant.

Oral metoclopramide (n=180) GIMOTI (n=45)

Patients in the GIMOTI group saved an average of $15,227 over the 6-month period.[7]

Study design[7]:

A retrospective real-world healthcare cost analysis of DGP patients (N=225) who were treated with oral metoclopramide or GIMOTI over a 6-month period. Patients were ≥18 years of age, well-matched across age, sex, DGP severity, and CCI.

Demographics[7]:

GIMOTI group: average age of 48 years, 75.6% female, average CCI* score 2.2, and DGP† severity of 44.4%

Oral metoclopramide group: average age of 49 years, 75% female, average CCI* score 2.3, and DGP† severity of 47.2%

*CCI predicts the risk of patient mortality associated with comorbidities; 2.2 indicates low risk.[6]

†DGP severity was defined as having experienced emergency department or inpatient hospitalization in the 6 months pre-index.[4]

INDICATION

Gimoti® (metoclopramide) nasal spray is indicated for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis.

Limitations of Use

GIMOTI is not recommended for use in pediatric patients, in patients with moderate or severe hepatic impairment, in patients with moderate or severe renal impairment, or in patients concurrently using strong CYP2D6 inhibitors.

Would your patients benefit from nasal administration with GIMOTI?

Learn more at GimotiRxHCP.com

IMPORTANT SAFETY INFORMATION

BOXED WARNING: TARDIVE DYSKINESIA

- **Metoclopramide can cause tardive dyskinesia (TD), a serious movement disorder that is often irreversible. The risk of developing TD increases with duration of treatment and total cumulative dosage.**
- **Discontinue GIMOTI in patients who develop signs or symptoms of TD. In some patients, symptoms may lessen or resolve after metoclopramide is stopped.**
- **Avoid treatment with metoclopramide (all dosage forms and routes of administration) for longer than 12 weeks because of the increased risk of developing TD with longer-term use.**

EVOKE PHARMA

Gimoti® (metoclopramide) nasal spray

Indication and Important Safety Information

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CONTRAINDICATIONS
GIMOTI is contraindicated in patients with a history of TD or a dystonic reaction to metoclopramide; when the stimulation of gastrointestinal motility might be dangerous (eg, in the presence of gastrointestinal hemorrhage, mechanical obstruction, or perforation); in patients with pheochromocytoma or other catecholamine-releasing paragangliomas (metoclopramide may cause a hypertensive/pheochromocytoma crisis, probably due to release of catecholamines from the tumor); in patients with epilepsy (metoclopramide may increase the frequency and severity of seizures); in patients with hypersensitivity to metoclopramide (reactions have included laryngeal and glossal angioedema and bronchospasm).

WARNING AND PRECAUTIONS
TARDIVE DYSKINESIA (TD): Metoclopramide can cause TD, a syndrome of potentially irreversible involuntary movements of the face or tongue, and sometimes of the trunk and/or extremities. The risk of developing TD and the likelihood that TD will become irreversible increases with the duration of treatment and the total cumulative dosage. The risk of developing TD is increased in the elderly, especially elderly women, and in patients with diabetes mellitus. Due to the risk of developing TD, avoid treatment with metoclopramide for longer than 12 weeks. GIMOTI is not recommended in geriatric patients as initial therapy. See Full Prescribing Information for switching geriatric patients on a stable dose of an alternative metoclopramide product to GIMOTI.

Other extrapyramidal symptoms (EPS): In addition to TD, metoclopramide may cause other EPS, parkinsonian symptoms, and motor restlessness. Advise patients to seek immediate medical attention if such symptoms occur and to discontinue GIMOTI.

Neuroleptic malignant syndrome (NMS): Metoclopramide may cause a potentially fatal symptom complex called NMS. Clinical manifestations of NMS include hyperpyrexia, muscle rigidity, altered mental status, and manifestations of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac arrhythmias). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. Patients with such symptoms should be evaluated immediately. Avoid GIMOTI in patients receiving other drugs associated with NMS, including typical and atypical antipsychotics.

Depression: Depression has occurred in metoclopramide-treated patients with and without a history of depression. Symptoms have included suicidal ideation and suicide. Avoid GIMOTI use in patients with a history of depression.

Hypertension: Metoclopramide may elevate blood pressure and should be avoided in patients with hypertension or in patients taking monoamine oxidase inhibitors (MAOIs). Discontinue GIMOTI in any patient with a rapid rise in blood pressure.

Fluid Retention: Because metoclopramide produces a transient increase in plasma aldosterone, patients with cirrhosis or congestive heart failure may be at risk of developing fluid retention and volume overload. Discontinue GIMOTI if any of these adverse reactions occur.

Hyperprolactinemia: As with other dopamine-D_2 receptor antagonists, metoclopramide elevates prolactin levels and may suppress pituitary gonadotropin secretion. This may inhibit reproductive function by impairing gonadal steroidogenesis in both female and male patients. Galactorrhea, amenorrhea, gynecomastia, and impotence have been reported with prolactin-elevating drugs, including metoclopramide.

Effects on the ability to drive and operate machinery: Metoclopramide may impair the mental and/or physical abilities required for the performance of hazardous tasks such as operating machinery or driving a motor vehicle. Concomitant use of CNS depressants or drugs associated with EPS may increase this effect (eg, alcohol, sedatives, hypnotics, opiates, and anxiolytics). Avoid GIMOTI or the interacting drug, depending on the importance of the drug to the patient.

ADVERSE REACTIONS
The most common adverse reactions in patients treated with GIMOTI are dysgeusia, headache, and fatigue. In patients receiving an equivalent oral dose of metoclopramide, the most common adverse reactions were restlessness, drowsiness, fatigue, and lassitude. Adverse reactions involving the nervous system occurred after stopping oral metoclopramide, including dizziness, nervousness, and headaches.

DRUG INTERACTIONS
Avoid concomitant use with antipsychotics, MAOIs, and central nervous system (CNS) depressants. Concomitant use with strong CYP2D6 inhibitors (eg, quinidine, bupropion, fluoxetine, paroxetine) is not recommended. Use with caution with dopaminergic agonists and drugs that increase dopamine concentration. Monitor for reduced therapeutic effect when used with drugs that may have opposing effects on gastrointestinal motility (eg, antiperistaltics, anticholinergics, opiates). Monitor patients receiving GIMOTI for increased blood glucose and adjust insulin dose regimen as needed.

USE IN SPECIFIC POPULATIONS
Pregnancy: Published studies do not report a consistent pattern or a consistently increased risk of pregnancy-related adverse outcomes with oral use of metoclopramide during pregnancy. There are potential risks to the neonate during delivery following exposure to metoclopramide in utero.

Lactation: Breastfed infants exposed to metoclopramide have experienced gastrointestinal adverse reactions, including intestinal discomfort and increased intestinal gas formation. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for GIMOTI and any potential adverse effects on the breastfed child from GIMOTI or from the underlying maternal condition.

Pediatric: Metoclopramide is not recommended for use in pediatric patients due to the risk of TD and other EPS as well as the risk of methemoglobinemia in neonates.

Geriatric: Elderly patients are more likely to have decreased renal function and may be more sensitive to the therapeutic or adverse effects of metoclopramide, especially older women. GIMOTI is not recommended as initial therapy.

Renal impairment: GIMOTI is not recommended in patients with moderate and severe renal impairment.

Hepatic impairment: GIMOTI is not recommended in patients with moderate or severe hepatic impairment.

NADH-cytochrome b_5 reductase deficiency: Metoclopramide-treated patients with NADH-cytochrome b_5 reductase deficiency are at an increased risk of developing methemoglobinemia and/or sulfhemoglobinemia.

CYP2D6 poor metabolizers: GIMOTI is not recommended in patients who are CYP2D6 poor metabolizers.

You may report side effects related to Evoke Pharma products by calling 1-833-4-GIMOTI (1-833-444-6684) or emailing GIMOTImedinfo@evokepharma.com. If you prefer to report side effects to the FDA, either visit www.FDA.gov/medwatch or call 1-800-FDA-1088.

References: 1. Chen YJ, Tang W, Ionescu-Ittu R, et al. Health-care resource use and costs associated with diabetic and idiopathic gastroparesis: a claims analysis of the first 3 years following the diagnosis of gastroparesis. *Neurogastroenterol Motil.* 2022;34(9):e14366. doi:10.1111/nmo.14366 **2.** Parkman HP, Yates K, Hasler WL, et al. Similarities and differences between diabetic and idiopathic gastroparesis. *Clin Gastroenterol Hepatol*. 2011;9(12):1056-1064. doi:10.1016/j.cgh.2011.08.013 **3.** Qayed E, Mufta M. Frequency of hospital readmission and care fragmentation in gastroparesis: a nationwide analysis. *World J Gastrointest Endosc*. 2018;10(9):200-209. doi:10.4253/wjge.v10.i9.200 **4.** Kunkel D, Quesenberry C, Shokoohi M, Kish J, Cyhaniuk A. Reducing real-world healthcare resource utilization for patients with diabetic gastroparesis (DGP) treated with metoclopramide nasal spray versus oral metoclopramide. Abstract presented at: Digestive Disease Week; May 7-9, 2023; Chicago, IL. **5.** Data on file. EVOKE PHARMA®. **6.** Walker G. Care management dashboards: calculation of risk scores. Rhode Island Quality Institute. Accessed January 15, 2024. https://riqi.org/wp-content/uploads/2021/04/Understanding-Risk-Scores.pdf **7.** McCallum R, Cline M, Shokoohi M, Marium S, Kish J, Kunkel DC. Superiority of nasal spray compared to orally administered metoclopramide in reducing healthcare costs for treating diabetic gastroparesis patients. Abstract presented at: American College of Gastroenterology Annual Scientific Meeting; October 20-25, 2023; Vancouver, BC.

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(metoclopramide)
nasal spray