Gimoti™
(metoclopramide)
nasal spray

FDA APPROVED

ABDOMINAL PAIN
EARLY SATIETY
VOMITING
BLOATING
NAUSEA

For patients with diabetic gastroparesis

Spray their symptoms away

GIMOTI nasal spray:

- Bypasses the GI tract[1,2]
- Delivers rapid nasal absorption[3]
- Provides relief from debilitating symptoms[1]

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.

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.**

Please see full Important Safety Information on pages 12-14 and accompanying Prescribing Information, including Boxed Warning and Medication Guide.

Diabetic gastroparesis—the burden is real

Many patients with diabetic gastroparesis require emergency medical care and hospitalization.[4-6]

80%
OF PATIENTS

say gastroparesis makes it harder to manage their diabetes[7]

Patients with diabetic gastroparesis have more ER visits and longer hospital stays than patients with other forms of gastroparesis[4,8]

Patients with diabetic gastroparesis are ready to try a metoclopramide nasal spray to find symptom relief.[3,*]

74%
OF PATIENTS
preferred nasal spray over other ways of taking medication

92%
OF PATIENTS
would use nasal metoclopramide if prescribed

96%
OF PATIENTS
considered nasal metoclopramide easy to use[†]

*These insights reflect findings from 98 patient interviews following a Phase 2 clinical trial for GIMOTI.
[†]Of these patients, 65% found nasal metoclopramide extremely easy to use while 31% found it somewhat easy to use.

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).

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In the diabetic gastroparesis treatment landscape…

GIMOTI hits all the marks[9-12]

	GIMOTI	Oral metoclopramide	Domperidone	Macrolide antibiotics[‡]
FDA approved for diabetic gastroparesis	✓	✓		
Nasal delivery, systemic availability	✓			
Avoids hepatic first-pass metabolism	✓			
Bypasses GI tract	✓			
Promotes gastric motility	✓	✓	✓	✓
Antiemetic	✓	✓	✓	
Recommended first-line treatment	✓	✓		

[‡]Erythromycin and other antibiotics.
GI=gastrointestinal.

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.

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The route to symptom relief

Nasal delivery of metoclopramide enables direct absorption into systemic circulation[1,2]

No first-pass hepatic metabolism prior to onset of action[1,2]

Bypasses the GI tract[1,2]

Relieves the debilitating symptoms of diabetic gastroparesis[1,2]

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.

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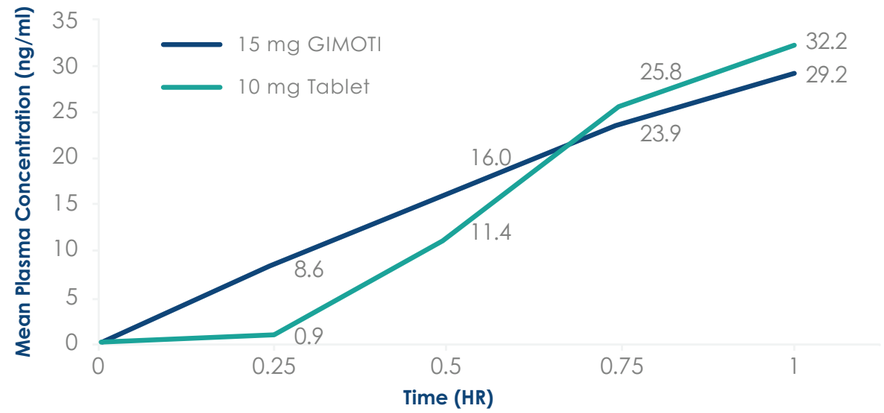
GIMOTI—nasal delivery for rapid absorption

Higher plasma concentration was achieved at 15 and 30 minutes with GIMOTI compared with oral metoclopramide[3]

Pharmacokinetic Study in Healthy Volunteers[3]



- Proportionally consistent results were seen with 10 mg and 20 mg doses of GIMOTI and 10 mg metoclopramide tablet in a Phase 1 bioavailability study in healthy volunteers[3]
- 15 mg GIMOTI spray results in similar systemic exposure and time to reach maximum plasma levels as 10 mg oral metoclopramide[1]
- GIMOTI can relieve symptoms of diabetic gastroparesis even during episodes of nausea, vomiting, or poor gastric emptying[13]
- GIMOTI may deliver therapeutic dose when oral antiemetics and prokinetics cannot[13]

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.

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.

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GIMOTI—Phase 3 trial overview[3]

Study design

Multicenter, randomized, double-blind (1:1), placebo-controlled, parallel-group, 28-day US study evaluated the efficacy, safety, and population pharmacokinetics

N=205 — 1:1 Randomization

- 10 mg metoclopramide nasal spray (n=102)
- Placebo (n=103)

Patient population

Adult female subjects (N=205) with symptoms of diabetic gastroparesis and delayed gastric emptying; metoclopramide nasal spray (n=102), placebo (n=103)

Primary endpoint

Change in baseline score to Week 4 of treatment, based on individual symptom scores for nausea, early satiety, prolonged fullness, bloating, and upper abdominal pain

Dosing arms

Two treatment arms: 10 mg metoclopramide nasal spray vs placebo, one spray before meals and at bedtime

Post-hoc analyses

Post-hoc efficacy analyses of a subgroup of subjects with moderate to severe disease at baseline (baseline score >2.7); metoclopramide nasal spray (n=52), placebo (n=53)

The marketed dose of Gimoti™ (metoclopramide) nasal spray is 15 mg, based on a pharmacokinetics study that demonstrated bioequivalence with a metoclopramide 10 mg tablet.

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.

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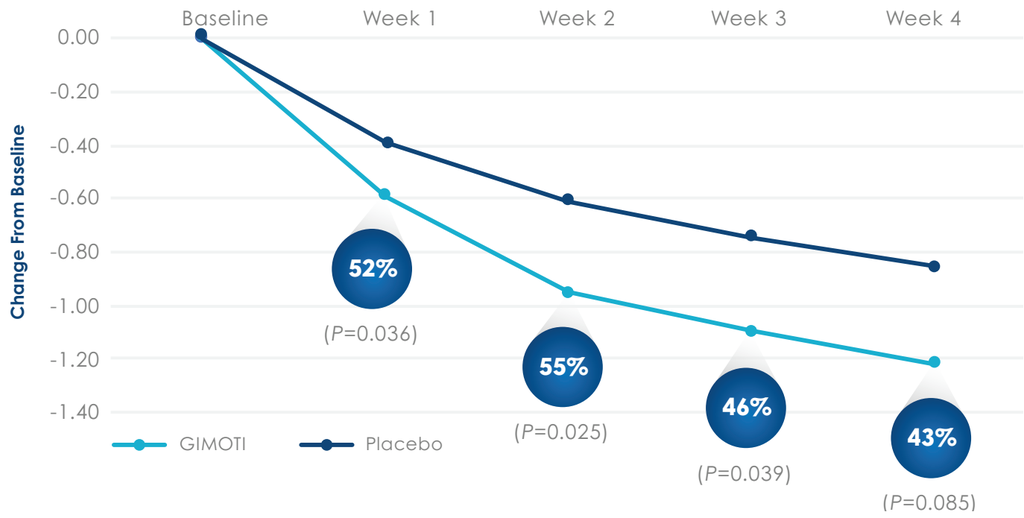
In patients with moderate to severe symptoms*…

GIMOTI provided early symptom relief[3]

Statistical significance seen at Weeks 1, 2, and 3 for patients treated with GIMOTI (n=52) compared with placebo (n=53)

Improvement in Total Symptom Score†



- **Up to 55%** greater improvement in total symptom score seen in patients treated with GIMOTI compared with placebo
- Primary efficacy was not achieved at Week 4 ($P<0.05$)

*Subgroup population includes all subjects who were randomized, with treatment assignment based on the randomized treatment.
†Post-hoc analysis conducted in patients with moderate to severe symptoms to assess response at each time point, Weeks 1 to 4.

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.

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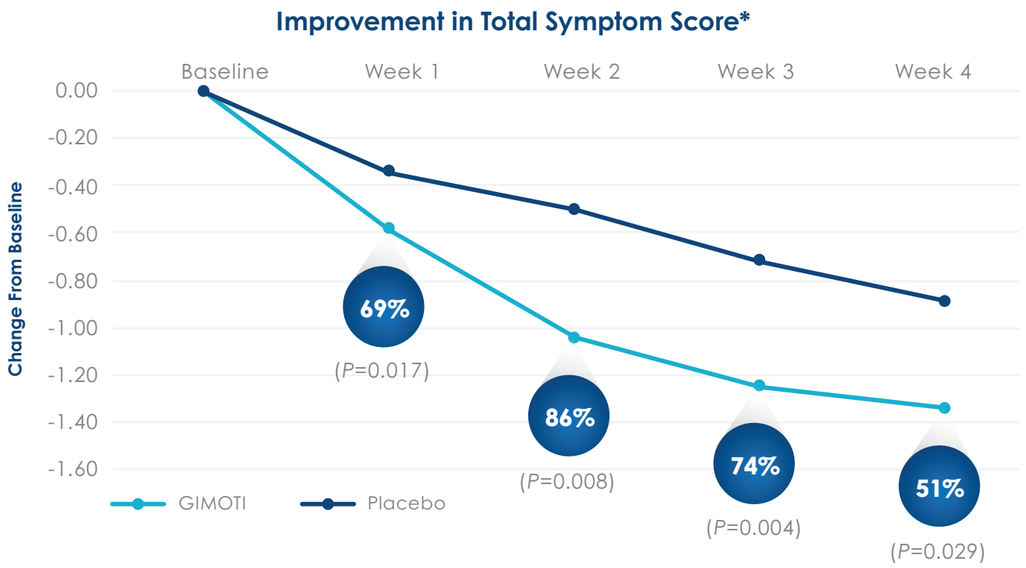
In completer patients with moderate to severe symptoms…

GIMOTI provided significant relief across all time points[3]

Statistical significance seen at Weeks 1 to 4 for patients treated with GIMOTI (n=43) compared with placebo (n=46)



*Post-hoc analysis conducted in patients with moderate to severe symptoms to assess response at each time point, Weeks 1 to 4.

- **Up to 86%** greater improvement in total symptom score seen in patients treated with GIMOTI compared with placebo

Completer population includes all randomized subjects who completed the 28-day treatment period.

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.

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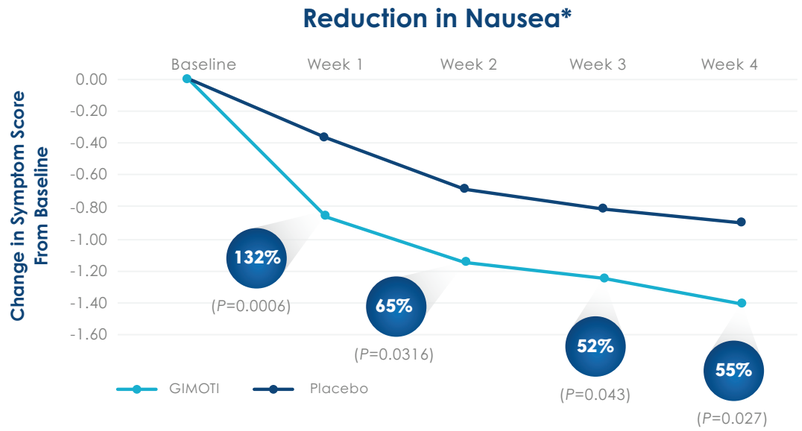
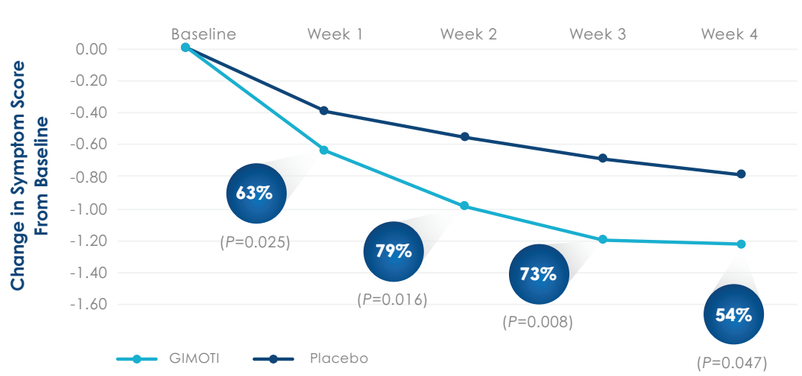
In patients with moderate to severe symptoms…

GIMOTI delivered significant relief of 2 key debilitating symptoms[3]



Up to 132% greater improvement in mean daily nausea score seen in patients treated with GIMOTI (n=52) compared with placebo (n=53)



Up to 79% greater improvement in mean daily abdominal pain score seen in patients treated with GIMOTI (n=52) compared with placebo (n=53)

*Post-hoc analysis conducted in patients with moderate to severe symptoms to assess response at each time point, Weeks 1 to 4.

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.

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In clinical trials…

GIMOTI demonstrated a favorable safety and tolerability profile

Adverse reactions[1]

- GIMOTI was generally well tolerated
- Dysgeusia was the most commonly reported adverse event, seen in 15% of patients taking GIMOTI

Other adverse reactions were similar to those reported for oral metoclopramide[1]

- Restlessness, drowsiness, fatigue, and lassitude were the most common adverse reactions in patients taking oral metoclopramide (occurring in ~10% of patients)

Monitoring for adverse reactions[1]

Monitor patients closely and discontinue GIMOTI in patients who develop signs or symptoms of TD. If patients cannot tolerate metoclopramide due to side effects, they should not use GIMOTI.

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.

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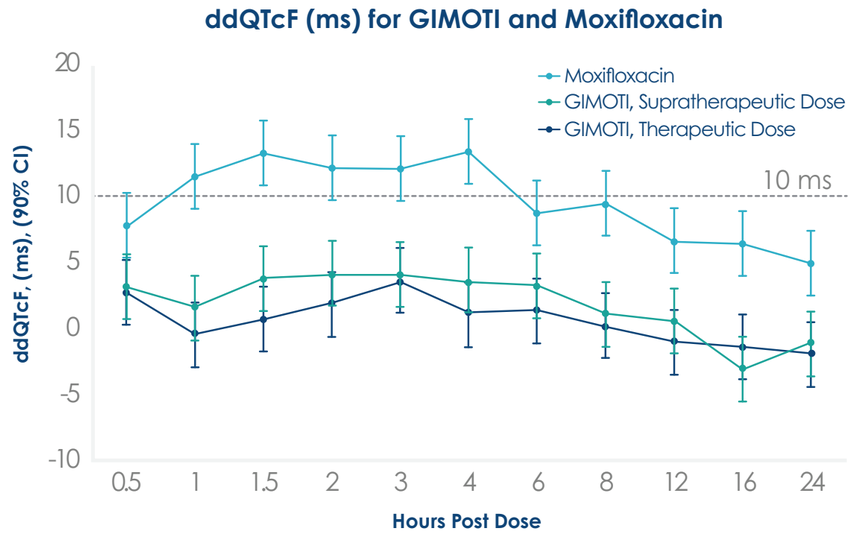
GIMOTI did not prolong QTc interval

Cardiac safety study in healthy subjects[14]



- GIMOTI is the only **FDA-approved metoclopramide product for gastroparesis with a thorough ECG study that showed no impact on QTc interval**[14,*]
- 5x the recommended dose of **GIMOTI did not prolong the QTc interval**[1]

*In a randomized, double-blind, positive-controlled thorough ECG study in 48 healthy subjects, a single administration of 80 mg metoclopramide nasal spray had no effect on the QTc interval.

ECG=electrocardiogram; ddQTcF=baseline- and placebo-adjusted change in QTcF; QTcF=QT interval corrected using Fridericia's formula.

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.

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Important Safety Information

INDICATION

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Limitations of Use

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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.

See accompanying full Prescribing Information, including Boxed Warning and Medication Guide.

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Important Safety Information (cont'd)

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.

Please see accompanying Prescribing Information, including Boxed Warning and Medication Guide.

References: 1. Gimoti™ (metoclopramide) nasal spray [prescribing information]. Solana Beach, CA: Evoke Pharma Inc; 2021. **2.** Pires A, Fortuna A, Alves G, Falcão A. Intranasal drug delivery: how, why and what for? *J Pharm Pharmaceut Sci*. 2009;12(3):288-311. **3.** Data on file. Evoke Pharma Inc. 2021. **4.** Dudekula A, O'Connell M, Bielefeldt K. Hospitalizations and testing in gastroparesis. *J Gastroenterol Hepatol*. 2011;26(8):1275-1282. **5.** Wadhwa V, Mehta D, Jobanputra Y, Lopez R, Thota PN, Sanaka MR. Healthcare utilization and costs associated with Gastroparesis. *World J Gastroenterol*. 2017;23(24):4428-4436. **6.** 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. **7.** Homko C, Siraj ES, Parkman HP. The impact of gastroparesis on diabetes control: patient perceptions. *J Diabetes Complications*. 2016;30(5): 826-829. **8.** Hirsch W, Nee J, Ballou S, et al. Emergency department burden of gastroparesis in the United States, 2006-2013. *J Clin Gastroenterol*. 2019;53(2): 109-113. **9.** Camilleri M, Parkman HP, Shafi MA, Abell TL, Gerson L. Clinical guideline: management of gastroparesis. *Am J Gastroenterol*. 2013;108(1):18-37. **10.** Krishnasamy S, Abell TL. Diabetic gastroparesis: principles and current trends in management. *Diabetes Ther*. 2018;9(Suppl 1): 1-42. **11.** Lee A, Kuo B. Metoclopramide in the treatment of diabetic gastroparesis. *Expert Rev Endocrinol Metab*. 2010;5(5):653-662. **12.** Patterson D, Abell T, Rothstein R, Koch K, Barnett J. A double-blind multicenter comparison of domperidone and metoclopramide in the treatment of diabetic patients with symptoms of gastroparesis. *Am J Gastroenterol*. 1999;94(5):1230-1234. **13.** Gajendran M, McCallum R. Metoclopramide nasal spray for management of acute and recurrent symptoms of diabetic gastroparesis in adults. *Expert Rev Endocrinol Metab*. 2021. https://doi.org/10.1080/17446651.2021.1886922. **14.** Carlson M, Alves W. Supratherapeutic dose of metoclopramide nasal spray to have no ECG effects in healthy males and female volunteers: results of the first metoclopramide thorough ECG study. Poster presented at: Digestive Disease Week; May 21-24, 2016; San Diego, CA.

EVOKE ASSIST™

Compassion in action

Ongoing commitment and support for you and your patients

ELIGIBLE COMMERCIALLY INSURED PATIENTS PAY $0 OR $50 FOR GIMOTI*

For your patients

- Eligible commercially insured patients pay $0 or $50 for GIMOTI*
- Coordinate free delivery of GIMOTI
- Pharmacy and nursing support to provide education about GIMOTI

For you and your practice staff

- Determine whether your patient's pharmacy benefits cover GIMOTI
- Assistance when needed as you submit prior authorizations
- Work with your office to collect missing information and ensure that all necessary paperwork is completed

You can reach EvokeAssist at 1-833-4-GIMOTI (1-833-444-6684), Monday to Friday from 9 AM to 8 PM ET. Assistance is available in English and Spanish.

*Patients are not eligible for copay assistance if they are enrolled in any state or federally funded healthcare programs, or where prohibited by law. Certain eligibility criteria apply; please see the Terms and Conditions available at pay.GimotiRx.com.

Gimoti™
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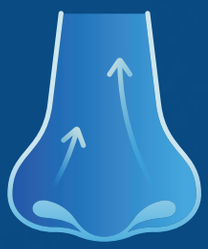
nasal spray

Prescribe GIMOTI today

Help your patients with diabetic gastroparesis spray their symptoms away



Novel treatment option

FDA Approved

- Relieves debilitating symptoms[1]
- Well tolerated[1]
- No impact on QTc interval[14]

Rapid nasal absorption[3]

Bypasses GI Tract[1,2]

- Direct absorption into systemic circulation
- Avoids hepatic first-pass metabolism
- Does not rely on gastric emptying

EvokeAssist™ Support

- Eligible commercially insured patients pay $0 or $50 for GIMOTI*
- Assistance when needed as you submit prior authorizations and any appeals

Gimoti™ (metoclopramide) nasal spray

EVOKE PHARMA

EVOKE ASSIST™ Compassion in action

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