

Gimoti® (metoclopramide) nasal spray is only available through the EVERSANA Life Sciences Specialty Pharmacy. Please fax this completed form to **1-800-593-7923** to prescribe GIMOTI or e-Prescribe by submitting an eRx to EVERSANA Life Sciences Services Specialty Pharmacy. See information below.

How to prescribe GIMOTI nasal spray

This Patient Enrollment Form is required to initiate treatment and **serves as the prescription for GIMOTI.**

Instructions

☐ Complete the following enrollment form in its entirety.

☒ Sign and date the form. **Prescriber MUST SIGN prescription.**

☐ Make a copy of the patient's medical insurance and pharmacy benefits cards, front and back, or fill out the patient's insurance information on page 2.

☐ Fax both pages of the completed form and copies of the patient's medical insurance and pharmacy benefits cards to EvokeAssist at **1-800-593-7923**.

OR

☐ e-Prescribe by submitting an eRx to EVERSANA Life Sciences Services Specialty Pharmacy.

e-Prescribing information: NCPDP#: 2635956 NPI#: 1548264591 Address: 17877 Chesterfield Airport Rd, Chesterfield, MO 63005.

Any missing information could delay patients receiving therapy.

Be sure to complete all information designated with an asterisk (*).

If you have any questions or comments, please call EvokeAssist at **1-833-4-GIMOTI (1-833-444-6684)**.



Please complete and fax this form, along with a coversheet, to **1-800-593-7923**. Fields marked with a (*) are required.
Ensure drug benefit card/information is included.

1 PATIENT INFORMATION (* INDICATES REQUIRED FIELD)

First Name* _____ MI _____ Last Name* _____

Sex* ☐ M ☐ F ☐ Prefer not to disclose

Mailing Address* _____ City _____ State _____ ZIP _____

Shipping Address (if different) _____ City _____ State _____ ZIP _____

Mobile Phone*[†] _____ Home Phone _____

Email Address* _____ Date of Birth* (MM/DD/YYYY) _____

[†]By providing my patient's mobile phone number, I authorize EVOKE PHARMA® to send non-telemarketing healthcare text messages to my patient to assist with treatment and to carry out financial or administrative activities related to my patient's healthcare, including service updates and medication reminders. Message and data rates may apply. I understand that this authorization is not a condition to my patient receiving their prescription.

2 INSURANCE INFORMATION (* INDICATES REQUIRED FIELD)

☐ No Insurance

**IF INSURED, PLEASE INCLUDE A COPY OF BOTH SIDES OF THE PATIENT'S PRESCRIPTION AND PRIMARY INSURANCE CARD(S).
OR FILL OUT THE PATIENT'S INSURANCE INFORMATION BELOW**

PRESCRIPTION INSURANCE _____ **PRIMARY INSURANCE** _____

Insurance Carrier* _____ Insurance Carrier* _____

Customer Service Phone* _____ Customer Service Phone* _____

Policy Holder Name* _____ Policy Holder Name* _____

Patient's Relationship to Subscriber _____ Patient's Relationship to Subscriber _____

Subscriber Date of Birth* _____ Subscriber Date of Birth* _____

Subscriber ID Number* _____ Subscriber ID Number* _____

Policy/Employer/Group Number* _____ Policy/Employer/Group Number* _____

Rx BIN# _____ Rx PCN# _____

Secondary Insurance Card? ☐ If Yes, Carrier _____

Subscriber ID Number (Secondary Insurance) _____ If applicable, please provide a copy of the patient's secondary insurance card.

Please complete and fax this form, along with a coversheet, to **1-800-593-7923**. Fields marked with a (*) are required.
Ensure drug benefit card/information is included.

3 HEALTHCARE PROVIDER (HCP) INFORMATION (* INDICATES REQUIRED FIELD)

HCP First Name* _____ MI _____ Last Name* _____
HCP NPI #* _____ State License #* _____ State Issued* _____
Address* _____ City* _____ State* _____ ZIP* _____
Phone* _____ Fax* _____
HCP Specialty _____ Office Contact Name _____ Phone _____ Ext. _____

☐ eRx submitted to EVERSANA Life Sciences Services Specialty Pharmacy.
e-Prescribing information: NCPDP#: 2635956 NPI#: 1548264591 Address: 17877 Chesterfield Airport Rd, Chesterfield, MO 63005.

4 PRESCRIPTION AND CLINICAL INFORMATION (* INDICATES REQUIRED FIELD)

Diagnosis or ICD-10-CM* _____ Known Drug Allergies* _____

Additional Patient Medications _____

☐ Basic Prescription

Labeled Instructions for Use: One spray (15 mg) in 1 nostril,
30 minutes before meals and at bedtime

**Rx Gimoti® (metoclopramide) nasal spray
(15 mg per spray)**

Directions* _____

Vial Qty: 1 Refills*: _____

☐ QuickStart Rx (optional)

The QuickStart prescription is optional, but opting for it will allow Evoke Pharma to automatically provide a 28-day supply in the event of a coverage delay. See page 4 for limits, terms, and conditions.

Labeled Instructions for Use: One spray (15 mg) in 1 nostril,
30 minutes before meals and at bedtime

**Rx Gimoti® (metoclopramide) nasal spray
(15 mg per spray)**

Directions* _____

Vial Qty: 1 Refills: 0

To aid in the communication with insurance companies, please check any of the below that apply:

- | | | |
|---|--|---|
| <input type="checkbox"/> Failed on oral metoclopramide (tablet or liquid) | <input type="checkbox"/> Dysphagia or oral motor difficulties | <input type="checkbox"/> Flares on current treatment |
| <input type="checkbox"/> Failed on antiemetics | <input type="checkbox"/> Persistent or chronic nausea and vomiting | <input type="checkbox"/> Prior ER visit or hospitalization for diabetic gastroparesis |
| <input type="checkbox"/> Positive sample trial of GIMOTI | | |

5 HCP ATTESTATION REQUIRED

I confirm that I have read and understand the HCP Attestation on page 4 of this form and agree to the terms explained therein.

☐ I have discussed the benefits and risks of metoclopramide with the patient, including the Boxed Warning.

SIGN HERE

Prescriber Signature _____ **Date (MM/DD/YYYY)** _____

Written signature only (print and sign); stamps and electronic signatures not acceptable. Dispense as written.

HCP ATTESTATION

I certify that I am prescribing this medically necessary medication for the named patient only and not under any understanding that I would recommend, prescribe, or use any Evoke Pharma product or service for any other person; the information provided is accurate to the best of my knowledge; I have the patient's signed HIPAA and state law authorization to share personal and medical information with Evoke Pharma and its agents to verify insurance and benefits coverage, seek prior authorization, provide financial assistance, facilitate provision of the medication, contact the patient with educational materials or to evaluate **EvokeAssist** effectiveness, and for Evoke Pharma's internal business purposes; I will not seek reimbursement for any medication or service provided through **EvokeAssist** from any government program or third-party insurer. I understand that Evoke may modify or terminate **EvokeAssist** at any time without notice; Evoke Pharma makes no representation or guarantee concerning coverage or reimbursement for any medication or service; and the information provided on this form is subject to random audits and verification.

If the patient needs **EvokeAssist** services, such as speaking with the nursing team or financial support, their consent is required. Given the challenges presented by COVID-19, we are providing three ways for the patient to consent:

- 1. ONLINE:** You or the patient can download the **EvokeAssist** Consent Form, available at GimotiRx.com, then fill it out and return it via fax or mail to the number or address indicated on this form.
- 2. BY MAIL:** Evoke Pharma will mail the patient a copy of the **EvokeAssist** Consent Form to sign and return in a postage-paid envelope.
- 3. BY PHONE:** Evoke Pharma can call the patient to obtain a recorded verbal authorization for enrollment in the **EvokeAssist** program.

QUICKSTART Rx PROGRAM TERMS & CONDITIONS

QuickStart Rx is not health insurance and is available for eligible **commercially insured patients only** who have been diagnosed with an FDA-approved indication for Gimoti®. No claim for reimbursement for product dispensed pursuant to this offer may be submitted to any third-party payer. QuickStart Rx is not available to patients covered under government plans such as Medicaid, Medicare, or other federal or state healthcare programs, including any state prescription drug assistance programs and the Government Health Insurance Plan, or for residents of Massachusetts, Michigan, Minnesota, Missouri, Ohio, or Rhode Island. Available up to a 28-day supply. The QuickStart Rx offer does not require, nor will it be made contingent on, purchase requirements of any kind. Evoke Pharma reserves the right to amend, rescind, or discontinue this program at any time without notification. QuickStart Rx can only be dispensed after a benefits investigation has been completed and a delay occurs in the prior authorization or appeals process. Offer good only in the United States and Puerto Rico. Prescription must be provided by a healthcare provider licensed in the United States or Puerto Rico. Additional eligibility criteria may apply. Contact **EvokeAssist** for details.

Important Safety Information

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.**

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-D₂ 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 b₅ reductase deficiency: Metoclopramide-treated patients with NADH-cytochrome b₅ 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.

Please see complete Prescribing Information, including Boxed Warning, and Patient Information.

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.



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