Gimoti (metoclopramide)

NEW PRODUCT SLIDESHOW

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Introduction

- **Brand name:** Gimoti
- **Generic name:** Metoclopramide
- **Pharmacologic class:** Dopamine-2 receptor antagonist
- **Strength and Formulation:** 15mg; per nasal spray (70 microliter); contains benzalkonium chloride
- **Manufacturer:** Evoke Pharma, Inc.
- **How supplied:** Nasal spray (9.8mL)—1
- **Legal Classification:** Rx

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Gimoti


Recommended Dosage: See prescribing information
Use only in the nose as directed by your healthcare provider
Keep out of the reach of children
Store at 20°C to 25°C (68°F to 77°F) excursions permitted 15°C to 30°C (59°F to 86°F)
Date of first opening
/ /
Discard unused portion 4 weeks after first use.
EVOKE PHARMA
Distributed by:
Evoke Pharma, Inc.
Solana Beach, CA 92075
Rev. 05-2020
NDC 72089-307-15
Gimoti™
(metoclopramide) nasal spray
15 mg per spray
FOR NASAL USE ONLY
Rx Only
Net Content 9.8 mL
112 metered sprays
EVOKE PHARMA
Gimoti™
(metoclopramide) nasal spray
15 mg per spray
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Net Content 9.8 mL
112 metered sprays
Discard unused portion 4 weeks after first use.

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Indication

- Relief of symptoms in adults with acute and recurrent **diabetic gastroparesis**.

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Limitations of Use

- **Not recommended for:**
  - Pediatric patients due to the risk of tardive dyskinesia and other extrapyramidal symptoms as well as the risk of methemoglobinemia in neonates.
  - Patients with moderate or severe hepatic (Child-Pugh B or C) and renal impairment (CrCl <60 mL/min).
  - Patients concurrently using strong CYP2D6 inhibitors due to the risk of increased drug exposure and adverse reactions.

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Dosage and Administration

- Prime before first use by releasing 10 sprays.
- **Avoid treatment for longer than 12 weeks.**
- *Adults less than 65 years of age*:
  - 1 spray (15mg) in 1 nostril, 30 minutes before each meal and at bedtime (maximum of 4 sprays daily) for 2 to 8 weeks.
- *Adults 65 years of age and older*:
  - Not recommended as initial therapy.
  - Require a lower starting dose.
  - Patients receiving an alternative metoclopramide product at a stable dosage of 10mg 4 times daily can be switched to Gimoti, depending on symptomatic response.

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Considerations for Specific Populations

- **Pregnancy:** Insufficient data to evaluate for a drug-associated risk.
  - *Clinical Considerations*: Monitor neonates for extrapyramidal signs.
- **Nursing mothers:** No data on the presence of metoclopramide in human milk following nasal administration.
  - *Clinical Considerations*: Monitor breastfeeding neonates for extrapyramidal signs and methemoglobinemia.
- **Pediatric**: Not established.
- **Geriatrics**: Require a lower starting dose (esp. women); not recommended as initial therapy.

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Considerations for Specific Populations

- **Renal impairment**: Not recommended for use in moderate or severe renal impairment (CrCl <60mL/min), including those receiving hemodialysis and continuous ambulatory peritoneal dialysis.
- **Hepatic impairment**: Not recommended for use in moderate or severe hepatic impairment (Child-Pugh B or C).
- **NADH-Cytochrome b_5 Reductase Deficiency**: Increased risk of methemoglobinemia and/or sulfhemoglobinemia.
- **CYP2D6 Poor Metabolizers**: Not recommended.

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Contraindications

- History of tardive dyskinesia or a dystonic reaction to metoclopramide.
- When stimulation of GI motility may be dangerous (eg, presence of GI hemorrhage, mechanical obstruction, or perforation).
- Pheochromocytoma or other catecholamine-releasing paragangliomas.
- Epilepsy.
- Hypersensitivity to metoclopramide.

Warnings and Precautions

- Increased risk of tardive dyskinesia (TD) with long-term use; avoid treatment for longer than 12 weeks.
  - Risk is increased among the elderly, especially elderly women, and in patients with diabetes mellitus.
- Discontinue immediately if signs/symptoms of TD, extrapyramidal symptoms, parkinsonian symptoms, motor restlessness, neuroleptic malignant syndrome, or rapid increase in blood pressure develop.

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Warnings and Precautions

- Avoid in patients with Parkinson disease, history of depression, or hypertension.
- Risk of fluid retention and volume overload in patients with cirrhosis or congestive heart failure (discontinue if these reactions occur).

Interactions

- Avoid concomitant drugs that can increase the frequency and severity of tardive dyskinesia, extrapyramidal symptoms, or neuroleptic malignant syndrome (eg, antipsychotics).
- Potentiated by strong CYP2D6 inhibitors (eg, quinidine, bupropion, fluoxetine, paroxetine); not recommended.
- Increased risk of hypertension with MAOIs; avoid.
- Increased risk of CNS depression with alcohol, sedatives, hypnotics, opiates, anxiolytics; avoid.
- Antagonized by drugs that impair GI motility (eg, antiperistaltic antidiarrheals, anticholinergics, opiates); monitor.

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Interactions

- Avoid concomitant dopaminergic agonists and other drugs that increase dopamine (eg, apomorphine, bromocriptine, cabergoline, levodopa, pramipexole, ropinirole, rotigotine).
- May potentiate succinylcholine, mivacurium, sirolimus, tacrolimus, cyclosporine; monitor and adjust dose.
- May antagonize digoxin (adjust dose), atovaquone, posaconazole (oral susp), fosfomycin; monitor.
- Concomitant insulin: monitor and adjust dose.

Adverse Reactions

- **Most common (≥5%)**: Dysgeusia, headache, fatigue.
- **Others**: TD, EPS, NMS, parkinsonism, akathisia, seizures, hallucinations, depression, hypertension (discontinue if occurs), fluid retention or volume overload (discontinue if occurs), hyperprolactinemia, hypersensitivity reactions.

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Mechanism of Action

- **Metoclopramide** stimulates motility of the upper GI tract without stimulating gastric, biliary, or pancreatic secretions.
- The exact mechanism of action of metoclopramide in the treatment of acute and recurrent diabetic gastroparesis has not been fully established.
- Metoclopramide increases the tone and amplitude of gastric contractions, relaxes the pyloric sphincter and the duodenal bulb, and increases peristalsis of the duodenum and jejunum resulting in accelerated gastric emptying and intestinal transit.

Pharmacokinetics

- The systemic absorption of metoclopramide after nasal administration is lower than that after oral administration given the same dose.
- Following nasal administration of Gimoti 15mg, the systemic exposure (Cmax and AUC) to metoclopramide and the time to reach Cmax were similar to orally administered metoclopramide 10mg.
- Mean half-life: approximately 8 hours.
- Metoclopramide undergoes enzymatic metabolism via oxidation as well as glucuronide and sulfate conjugation reactions in the liver.
- The major oxidative metabolite of metoclopramide is formed primarily by CYP2D6.

Clinical Trials

- The effectiveness of Gimoti has been established based on studies of oral metoclopramide for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis.

New Product Monograph

- For more information view the product monograph available at:

https://www.empr.com/drug/gimoti/