RXADVANCE
2 Park Central Drive
Southborough, MA 01772

CLINICAL UPDATE

Brand Name	Gimoti®
Generic Name	metoclopramide hydrochloride
Drug Manufacturer	Evoke Pharma, Inc

Clinical Update

Clinical Update: FDA Approves Gimoti® (metoclopramide) Nasal Spray for Diabetic Gastroparesis

FDA Approval Date: June 19, 2020

Launch Date: Q4 of 2020

Overview

Gimoti® is a dopamine-2 (D_2) antagonist. It is indicated for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis.

It is not recommended for use in:

- Pediatric patients due to the risk of developing tardive dyskinesia (TD) and other extrapyramidal symptoms as well as the risk of methemoglobinemia in neonates;
- Moderate or severe hepatic impairment (Child-Pugh B or C), moderate or severe renal impairment (CrCl < 60 mL/minute), and patients concurrently using strong CYP2D6 inhibitors due to the risk of increased drug exposure and adverse reactions.

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.

Dose & Administration

ADULTS

Adults < age 65 years: The recommended dosage is 1 spray (15 mg) in one nostril, 30 minutes before each meal and at bedtime (maximum of 4 sprays daily) for 2 to 8 weeks, depending on symptomatic response.

Adults ≥ age 65 years: Gimoti® is not recommended in geriatric patients as initial therapy. Geriatric patients receiving an alternative metoclopramide product at a stable dosage of 10 mg four times daily can be switched to Gimoti®. Refer to adult dosing.

DOSAGE FORM(S) AND STRENGTH(S)

Nasal Spray: 15 mg metoclopramide in each 70-microliter spray