## Gimoti™ (metoclopramide) – New drug approval

- On June 19, 2020, Evoke Pharma announced the FDA approval of Gimoti (metoclopramide), for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis.

- Gimoti is not recommended for use in:

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

- Gimoti is the first intranasal formulation of metoclopramide. Oral metoclopramide is available generically as an orally disintegrating tablet (ODT), solution, and tablet.

    - The ODT, solution, and tablet formulations are approved for symptomatic gastroesophageal reflux disease, and diabetic gastroparesis.

- 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.

- Gimoti carries a boxed warning for tardive dyskinesia.

- Gimoti is contraindicated:

    - In patients with a history of tardive dyskinesia or a dystonic reaction to metoclopramide
    - When 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
    - In patients with epilepsy
    - In patients with hypersensitivity to metoclopramide.

- Additional warnings and precautions for Gimoti include other extrapyramidal symptoms; neuroleptic malignant syndrome; depression; hypertension; fluid retention; hyperprolactinemia; effects on the ability to drive and operate machinery; and risk of adverse reactions with Gimoti in patients with moderate or severe renal and hepatic impairment, CYP2D6 poor metabolizers and patients taking strong CYP2D6 inhibitors.

- The most common adverse reactions (≥ 5%) with Gimoti use were dysgeusia, headache, and fatigue.

- In adults less than 65 years of age, the recommended dosage of Gimoti is 1 spray (15 mg) in one nostril, 30 minutes before each meal and at bedtime (maximum of four times daily) for 2 to 8 weeks, depending on symptomatic response.

- Adults 65 years of age and older may be more sensitive to the adverse effects of metoclopramide and require a lower starting dosage. 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 1 spray (15 mg) in one nostril, 30 minutes

Continued . . .

before each meal and at bedtime (maximum four times daily) for 2 to 8 weeks, depending on symptomatic response. Treatment with metoclopramide (all dosage forms and routes of administration) for longer than 12 weeks should be avoided.

- Evoke Pharma plans to launch Gimoti in the fourth quarter of 2020. Gimoti will be available as a nasal spray containing 15 mg metoclopramide in each 70-microliter spray.

**optumrx.com**