

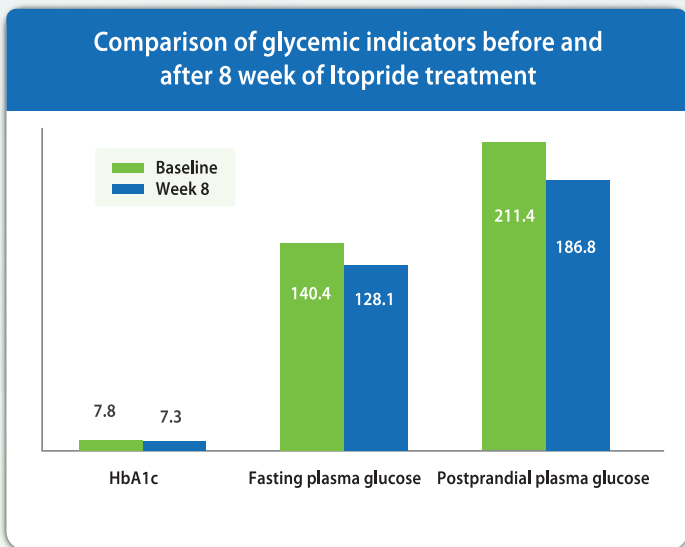
# A prospective multicentric postmarketing observational study to characterize the patient population with reduced gastrointestinal motility among Indian diabetic patients receiving Itopride: the progress study

- Diabetic gastroparesis affects 20-50% of diabetic patients, leading to delayed gastric emptying and unstable blood glucose levels.
- Itopride, a prokinetic agent, improves gastrointestinal motility and helps stabilize glucose levels by enhancing gastric emptying.

This study demonstrates that itopride effectively relieves symptoms and improves glycemic control, offering a comprehensive treatment approach for diabetic gastroparesis.

Study design		Multicentric, prospective observational		
<b>Population</b>  <b>41 Diabetic patients</b>	<b>Intervention</b> Itopride 200 mg TID vs placebo	<b>Duration</b>  8 weeks	<b>Outcome</b> Significant improvement in: <ul style="list-style-type: none"> <li>➤ GI symptoms (bloating, nausea and postprandial fullness)</li> <li>➤ Quality of life (*PAGI-QoL score)</li> <li>➤ Glycemic indices (HbA1c, fasting plasma glucose, postprandial glucose)</li> </ul>	

\* Patient Assessment of Upper Gastrointestinal Disorders- Quality of Life



### Conclusion

- Itopride effectively alleviates symptoms of diabetic gastroparesis, including bloating, nausea, and postprandial fullness (P < 0.001).
- Significant improvements in glycemic control were observed, with reductions in HbA1c (P < 0.001), fasting plasma glucose (P = 0.004), and postprandial glucose (P = 0.004).
- The treatment was well-tolerated, with no adverse drug reactions, reinforcing itopride's safety and efficacy as a therapeutic option for diabetic gastroparesis.

Ref: Rai RR, Choubal CC, Agarwal M, Khaliq AM, Farishta FJ, Harwani YP, et al. A prospective multicentric postmarketing observational study to characterize the patient population with reduced gastrointestinal motility among Indian diabetic patients receiving itopride: The PROGRESS study. Int J App Basic Med Res. 2019;9(3):148-153.

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# Itopride hydrochloride

next generation, dual acting gastrointestinal prokinetic for fast & satisfactory relief from symptoms of gastric motility disorders

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**Dual Action. Fast Relief.**

# Drug Review

## Gastric motility disorder<sup>1,2,3,4</sup>

- Gastrointestinal (GI) motility disorders encompass a wide array of signs and symptoms and functional dyspepsia (FD) and gastroparesis are the main associated syndromes.
- FD diagnosed based on the Rome IV criteria- The presence of one or more of the following symptoms: epigastric pain or burning, early satiety, and postprandial fullness in the absence of structural disease.
- Prokinetic agents are the mainstay therapy for FD and gastroparesis, to improve gastric emptying and relieve symptoms.
- Conventional prokinetics (e.g. domperidone, metoclopramide) only block dopamine D2 receptors (DD2R) but have no effect on acetylcholinesterase. Thereby, complete relief of functional dyspepsia symptoms can not be achieved.

## Itopride (Itonorm) - next generation dual acting gastrointestinal prokinetic

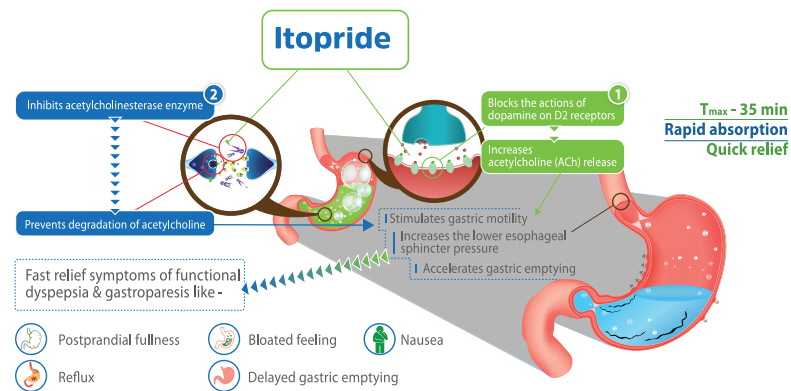


Figure: Mechanism of action of Itopride

## Proven Safety and results<sup>6,7,8,9,10</sup>

- Itopride does not cross the BBB hence exerts no CNS effects (e.g. headache, nausea, dyskinesia). It does not cause hyperprolactinemia and has no impact on QT interval, as a result doesn't affect heart rate.
- The drug is metabolized by flavin-containing monooxygenase 3 (FMO3) pathway hence no drug-drug interactions with CYP450 inhibitors.
- Itopride is a relatively safer molecule compared with other prokinetics, with no extrapyramidal symptoms or cardiotoxicity concerns, can be used for long-term in GI motility disorders either alone or in combination with other drugs.
- Itopride has good efficacy in terms of global patients' assessment, postprandial fullness, and early satiety in the treatment of patients with FD and shows a low rate of adverse reactions.
- Significant improvement in glycaemic indices was also evident posttreatment with itopride. Itopride showed effectiveness in addressing symptoms of reduced GI motility in patients with diabetes, with improved quality of life.
- Itopride 100 mg t.i.d is effective in decreasing pathologic reflux in patients with GERD and therefore it has the potential to be effective in the treatment of this disease.

Ref.: 1. Brian E. Lacy, Kirsten Weiser; Gastrointestinal Motility Disorders: An Update. Dig Dis 1 July 2006; 24 (3-4): 228-242.; 2. the treatment of dysmotility. EMJ Gastroenterol. 2014;3:42-7.; 3. Oshima T. Functional Dyspepsia: Current Understanding and Future Perspective. Digestion. 2024;105(1):26-33.; 4. Camilleri M, Atieh J. New Developments in Prokinetic Therapy for Gastric Motility Disorders. Front Pharmacol. 2021 Aug 24;12:711500.; 5-Dite, Petr & Rydlo, Martin & Dockal, Milan & Martinek, Arnost. (2014); 6-7. Huang X, Lv B, Zhang S, Fan YH, Meng LN. Itopride therapy for functional dyspepsia: a meta-analysis. World J Gastroenterol. 2012 Dec 28;18(48):7371-7.; 8-a new prokinetic, in patients with mild GERD: a pilot study. World J Gastroenterol. 2005 Jul 21;11(27):4210-4.; 9. Rai RR, Choubal CC, Agarwal M, Khaliq AM, Farišta FJ, Harwani YP, Kumar SY. A Prospective Multicentric Postmarketing Observational Study to Characterize the Patient Population with Reduced Gastrointestinal Motility among Indian Diabetic Patients Receiving Itopride: The Progress Study. Int J Appl Basic Med Res. 2019 Jul-Sep;9(3):148-153.; 10. Chaudhuri, S. (2023). Role and safety of prokinetic drugs in the treatment of upper gastrointestinal motility disorders: an Indian perspective. International Journal of Research in Medical Sciences, 11(10), 3937-3944.