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# A prokinetic agent with dual effects: Itopride in the treatment of dysmotility.

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- Functional dyspepsia accounts for nearly 60% of patients with dyspeptic symptoms, with delayed gastric emptying present in ~30% of cases. Impaired gastroduodenal coordination leads to postprandial fullness, early satiety, and bloating.
- Many available prokinetics are limited by cardiac risks (QT prolongation) or central nervous system adverse effects. A safe agent that effectively enhances upper GI motility without these limitations remains clinically necessary.
- This review evaluated the efficacy and safety of itopride across randomized trials and meta-analytic evidence. Itopride's dual mechanism (D2 antagonism + acetylcholinesterase inhibition) provides a rational approach to dysmotility management.

## Study design: Meta-analysis of 9 randomized controlled trials

### Population

Adults with functional dyspepsia (n=2,620)

### Setting

Multinational, multicenter trials

### Intervention

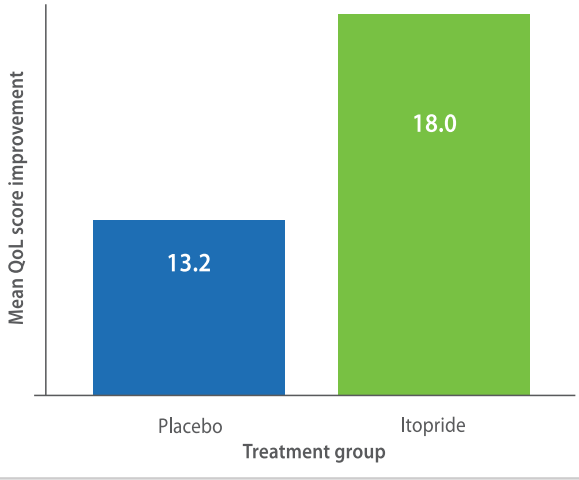
Itopride 50 mg TID
vs
placebo / domperidone / mosapride

### Key Findings

Significant improvement in global symptom relief:

- Postprandial fullness (p=0.02)
- Early satiety (p=0.04)
- Superior efficacy of itopride than placebo, domperidone & mosapride

## Quality of life improvement in functional dyspepsia




## Conclusion

- Itopride consistently improved global symptom scores, postprandial fullness, and early satiety across randomized trials and meta-analytic evidence. Symptom response rates increased significantly with continued therapy.
- Its dual action dopamine D2 receptor antagonism and acetylcholinesterase inhibition enhances coordinated upper GI motility. This targeted mechanism addresses core pathophysiology of functional dyspepsia.
- Itopride does not cross the blood-brain barrier and does not prolong the QT interval. Clinical studies demonstrate tolerability comparable to placebo.

**Ref:** Dite P et al. A Prokinetic Agent with a Dual Effect – Itopride – in the Treatment of Dysmotility. EMJ Gastroenterol. 2014;3:42-47

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

**Itonorm®**
Itopride hydrochloride 50 mg tablet

***Dual Action. Fast Relief.***

Drug Review

## Gastric motility disorder[1,2,3,4]

- 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

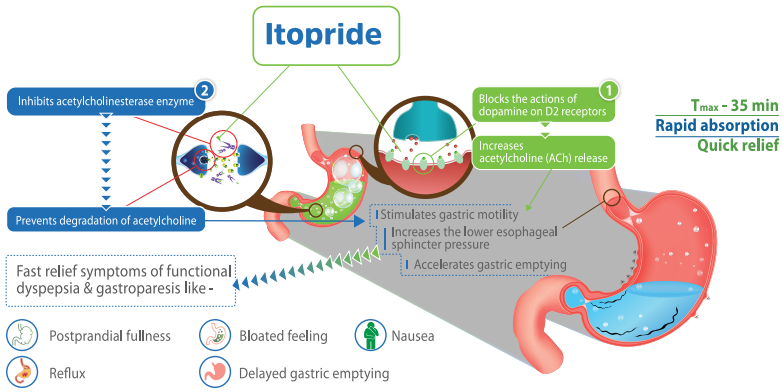



Figure: Mechanism of action of Itopride

## Proven Safety and results[6,7,8,9,10]

- Itopride does no 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 glycemic 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, Farishta 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.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