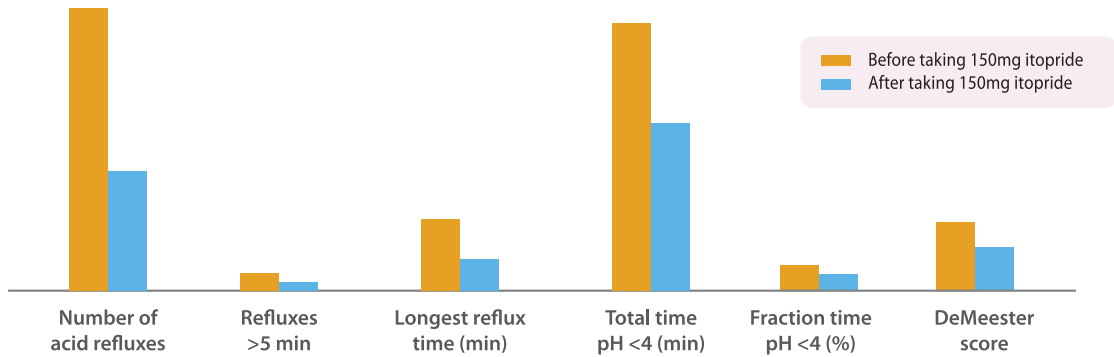


# Effect of itopride, a new prokinetic, in patients with mild GERD: A pilot study

- ▶ Gastro-esophageal reflux disease (GERD) is a chronic condition driven largely by esophageal motor dysfunction, impaired clearance of refluxed acid, and delayed gastric emptying.
- ▶ Traditional prokinetics such as metoclopramide, domperidone, and cisapride have shown limited efficacy or raised safety concerns.
- ▶ Itopride, a novel prokinetic agent with dual dopamine D2 antagonism & acetylcholinesterase inhibition, enhances gastric motility, accelerates gastric emptying & improves esophageal clearance. Hence, itopride offers a promising therapeutic option for GERD patients beyond conventional acid suppression.

Study design		Prospective, randomized, open-label, 4-week pilot study		
Population	Indication	Intervention	Outcomes	
<p>26 patients</p>	GERD	Itopride 150 mg/day or 300 mg/day (divided t.i.d.) for 4 weeks	<ul style="list-style-type: none"> <li>■ Significant improvement in GERD symptoms.</li> <li>■ Reduction in acid reflux parameters (pH&lt;4 time, DeMeester score).</li> <li>■ Well tolerated with no serious adverse events.</li> </ul>	

## Effects of Itopride on GERD



- ▶ This pilot study demonstrated that itopride significantly improves GERD symptoms and reduces pathological acid reflux, particularly at the 150 mg dose, with no serious adverse events.
- ▶ Improvements were evident in acid exposure time, DeMeester score, and reflux episodes, confirming both symptom relief and objective efficacy. With its favorable safety profile and dual mechanism of action, itopride can be considered an effective and well-tolerated treatment option for patients with mild GERD.

Ref: World J Gastroenterol 2005;11(27):4210-4214

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Itopride hydrochloride 50 mg tablet



# 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

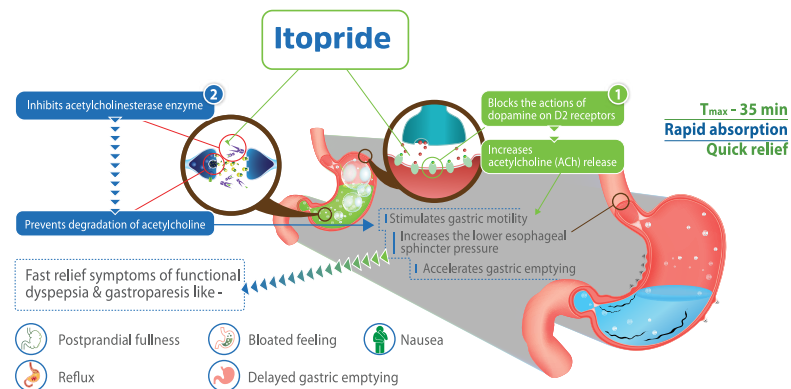


Figure: Mechanism of action of Itopride

## 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.

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