

Itogest

Itopride Hydrochloride INN

Composition

Itogest 50 Tablet: Each film coated tablet contains Itopride Hydrochloride INN 50 mg.

Pharmacology

Itopride Hydrochloride is a potent dopamine-2 antagonist and an acetylcholine esterase inhibitor. It increases acetylcholine concentrations by inhibiting dopamine D2 receptors and acetylcholinesterase. Higher acetylcholine increases GI peristalsis, increases the lower esophageal sphincter pressure, stimulates gastric motility, accelerates gastric emptying, and improves gastro-duodenal coordination.

Indication

It is indicated for the treatment of- Gastrointestinal symptoms in chronic gastritis:

- feeling of an enlarged abdomen
- upper abdominal pain
- anorexia
- heartburn
- nausea and vomiting

Dose & Administration

a) *Route of administration:* Oral

The recommended adult dose: 50 mg of Itopride Hydrochloride administered orally three times daily. The dose may be reduced according to the patient's age and symptoms. It should be taken before meals.

Hepatic function disorder and Jaundice: Hepatic function disorder and jaundice with increased AST(GOT), ALT(GPT) and g-GTP etc., may occur, and close observation should be made. If abnormalities occur, the drug should be discontinued and appropriate therapeutic measures implemented.

Contra-indication

This Medicine is contraindicated in:

Hypersensitivity to the active substance or to any of the excipients on this preparation. This should not be used in patients in whom increased gastrointestinal motility could be harmful, e.g., in patients with gastrointestinal hemorrhage, mechanical obstruction or perforation.

Warning & Precaution

This drug should be used with caution since it enhances the action of acetylcholine. This drug should not be consumed continuously for an extended period when no improvement of gastrointestinal symptoms is observed.

Side effects

a) *Common:* Diarrhea, constipation, headache, abdominal pain, irritated feeling and dizziness.

b) *Rare:* Spontaneous milk secretion and breast enlargement in male & decrease in white blood cells.

Use in Pregnancy & Lactation

Pregnancy: Safety of Itopride in pregnancy was not verified. Therefore, itopride can be used in pregnant women or women in that pregnancy cannot be excluded only if therapeutic benefits outweigh possible risks considerably.

Lactation: Data about excretion in mother milk is known only in animals. Because of lack of experience with use of itopride during breast-feeding itopride it is not recommended for breast-feeding women.

Use in Children & Adolescents

The safety and efficacy of Itopride Hydrochloride in children and adolescents have not been established. Therefore, the administration of Itopride Hydrochloride is not recommended in children and adolescents below 18 years of age.

Drug Interaction

a) *With medicine:* When co-administered with Itopride Hydrochloride gastrointestinal motility inhibitory action of Anticholinergic pharmacologically decreases the activity of the drug like Anticholinergic Drugs, Tiquizium bromide, Scopolamine butyl bromide, Timepidium bromide, etc.

b) *With food & others:* It may interact with grapefruit juice. Therefore, avoid consuming grapefruit juice with Itopride Hydrochloride as it may increase the risk of adverse effects.

Overdose

In case of excessive overdose, the usual measures of gastric lavage and symptomatic therapy should be applied.

Storage

Store below 30°C. Protect from light & moisture. Keep all medicines out of reach of children.

Packing

Itogest 50 Tablet: Each box contains 60 (6x10's) tablets in Alu-Alu blister pack.



Manufactured by

ONE PHARMA LTD.

C-23-24, BSCIC I/A

Bogura, Bangladesh

LF0128

IGT Rev.01