

Itopa

Itopride Hydrochloride INN

COMPOSITION

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

PHARMACOLOGY

Itopride Hydrochloride is a potent dopamine-2 antagonist and an acetylcholinesterase 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

Gastrointestinal symptoms in chronic gastritis (bloating feeling, upper abdominal pain, anorexia, heartburn, nausea and vomiting)

DOSAGE AND ADMINISTRATION

The usual adult dose for oral use is 50 mg of Itopride Hydrochloride administered orally three times daily before meals. The dose may be reduced according to the patient's age and symptoms.

CONTRAINDICATION

Itopride Hydrochloride is contraindicated in patients with hypersensitivity to itopride or any excipient of the product.

WARNING AND 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 EFFECT

Some side effects may be reported like - Rash, constipation, headache, diarrhea etc.

USE IN SPECIAL POPULATION

• USE IN PREGNANCY AND LACTATION

Pregnancy: Itopride Hydrochloride should be used in pregnant women or women having possibilities of being pregnant only if the expected therapeutic benefit is thought to outweigh any possible risk.

Breastfeeding: It is advisable to avoid the administration of Itopride Hydrochloride to nursing mothers. However, when the administration is indispensable, nursing should be discontinued.

• USE IN THE ELDERLY

Since the elderly often have a physiological hypofunction, they are prone to adverse reactions and should thus be closely monitored. If adverse reactions are evident, appropriate measures such as reduction or cessation of the drug should be implemented.

• USE IN PEDIATRIC POPULATION

The safety of Itopride Hydrochloride in children has not been established.

• HEPATIC & RENAL IMPAIRMENT

Patients with reduced hepatic or renal functions should be carefully monitored and in case of adverse reactions it is necessary to take appropriate measures, as e.g. to reduce the dosage or to discontinue the therapy.

DRUG INTERACTION

Itopride Hydrochloride should be administered with care when co-administered with Anticholinergic drugs like- Tiquizium bromide, scopolamine butyl bromide, timepidium bromide etc.

OVERDOSE

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

STORAGE

- Store below 30°C, keep in dry place & protect from light.
- Keep out of reach of children.

PACKING

Itopa-50 Tablet: Each box contains 60 Tablets in Alu-Alu blister pack.

Manufactured by:
ARISTOPHARMA LTD.
Shampur-Kadamtai I/A, Dhaka-Bangladesh

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