Exipid®

Itopride Hydrochloride

COMPOSITION :

Exipid® 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:

Gastrointestinal symptoms in chronic gastritis (feeling of an enlarged abdomen, 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. The dose may be reduced according to the patient's age and symptoms.

METHOD OF ADMINISTRATION:

Itopride Hydrochloride should be taken before meals.

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 EFFECTS:

Following side effects have been reported with the use of Itopride Hydrochloride: Rash, giddiness,exhaustion, back or chest pain, increased salivation, constipation, headache, sleeping disorders, dizziness, galactorrhea & gynecomastia.

USE IN PREGNANCY AND LACTATION :

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 hypo function, 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 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.

USE IN SPECIAL POPULATION:

Shock and anaphylactoid reactions

Shock and anaphylactoid reactions may occur & close observation should be made. If hypotension, dyspnea, larynx edema, urticaria, pallor, diaphoresis etc. occur, the drug should be discontinued and appropriate measures implemented.

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.

DRUG INTERACTION :

Itopride Hydrochloride should be administered with care when co-administered with the following drugs:

Drugs	Clinical symptoms	Mechanism & risk factors
Anticholinergic drugs, Tiquizium bromide, Scopolamine butyl bromide, Timepidium bromide etc.	There is a possibility of reducing activity of Itopride Hydrochloride which activates gastrointestinal motility (cholinergic action).	Gastrointestinal motility inhibitory action of anticholinergic decreases the activity of the drug.

OVERDOSAGE:

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

STORAGE:

Do not store above 30° C. Protect from light. Keep out of reach of children.

PACKAGING :

Exipid® 50 Tablet: Each box contains 5 x 10's tablets in Alu-Alu blister pack.

Manufactured by
Team Pharmaceuticals Ltd.
B 75-79, BSCIC, Rajshahi, Bangladesh

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