120mm

181mm

Itosel

Tablet 50mg

(I t o p r i d e)

آئیٹوسیل

ٹیبلیٹ ۵۰ ملی گرام

(ایٹوپرائیڈ)

COMPOSITION:

Each film coated tablet contains:

Itopride HCl .....50 mg

(Innovator's specifications)

DESCRIPTION:

ITOSEL (Itopride HCl) is a prokinetic benzamide derivative. It inhibits dopamine and have a gastro kinetic effect.

MECHANISM OF ACTION:

Itopride HCl increases the release of acetylcholine through dopamine D2-receptor antagonistic activity and inhibit s decomposing released acetylcholine through its acetylcholine esterase (AChE) inhibitory action, resulting in enhancement of gastrointestinal activity. Higher acetylcholine increases GI peristalsis, increases the lower esophageal sphincter pressure, stimulates gastric motility, accelerates gastric emptying and improves gastro-duodenal coordination.

INDICATIONS:

ITOSEL (Itopride HCl) tablet is used in the treatment of gastrointestinal symptoms of:

- Functional Dyspepsia
- Non-ulcer Dyspepsia (chronic gastritis) i.e. - Sensation of bloating, Early satiety, Upper abdominal pain or discomfort, Anorexia, Heartburn, Nausea and Vomiting

DOSAGE & ADMINISTRATION:

The usual adult dosage for oral use is 150 mg of ITOSEL (Itopride HCl) daily in three divided doses before meals. The dose may be reduced according to patient's age and symptoms.

PHARMACOKINETICS:

Absorption

Itopride HCl is rapidly and almost completely absorbed from the gastrointestinal tract. Relative bioavailability is calculated to be 60% due to liver first pass metabolism. Peak plasma levels (Cmax 0.28 g/mL) are reached after 0.5-0.75 hr after 50mg of itopride HCl. Following multiple oral doses ranging from 50-200 mg 3 times daily, itopride HCl and its metabolites showed linear pharmacokinetics over a treatment period of 7 days, with minimal accumulation.

Distribution

Approximately 96% of itopride HCl is bound to plasma proteins. Albumin accounts for most of the binding. 1-acid glycoprotein accounts for <15 % of binding.

Metabolism

Itopride HCl undergoes extensive hepatic metabolism in humans. Three metabolites have been identified, of which only one exerts minor activity without pharmacological relevance (approximately 2-3% of that of itopride HCl). The primary metabolite in humans is the N-oxide generated by oxidation of the tertiary amine N-dimethyl group. Itopride HCl is metabolized by a flavin-dependent monooxygenase (FMO3).

Excretion

Itopride HCl and its metabolites are primarily excreted in the urine. The urinary excretions of itopride HCl and its N-oxide were 3.7% and 75.4%, respectively, after oral administration of a single therapeutic dose. The terminal phase half-life of itopride HCl is approximately 6 hrs.

PRECAUTIONS:

Itopride HCl should be used with caution since it enhances the action of acetylcholine. Also caution is advised in treatment of patients suffering from Parkinson's disease and conditions involving dopamine regulation issues.

Itopride HCl should not be used aimlessly for a long term when no improvement of gastrointestinal symptoms is observed.

Pregnancy and Nursing Mothers

Itopride HCl should be used in pregnant women or in women who may possibly be pregnant only if the expected therapeutic benefits outweigh the possible risks associated with treatment. The safety of itopride HCl in pregnant women has not been established. It is ideal not to use itopride HCl in women during lactation, but if it is necessary, breast feeding should be avoided during the treatment of itopride HCl.

ADVERSE REACTIONS:

The following adverse events have been reported in patients receiving itopride HCl:

Blood and Lymphatic System Disorders:

Leukopenia and thrombocytopenia.

Immune System Disorders:

Anaphylactoid reaction.

Endocrine Disorders:

Increased prolactin level and gynecomastia.

Nervous System Disorders:

Dizziness, headache and tremor.

Gastrointestinal Disorders:

Diarrhea, constipation, abdominal pain, increased saliva, and nausea.

Hepatobiliary Disorder:

Jaundice.

Skin and Subcutaneous Tissue Disorders:

Rash, redness and itching

Investigations:

Increased AST (SGOT), increased ALT (SGPT), increased γ-GTP, increased alkaline phosphatase and increased bilirubin.

DRUG INTERACTIONS:

Itopride HCl has gastrokinetic effects, therefore, it could influence the absorption of concomitantly orally administered drugs. Particular caution should be taken with drugs with a narrow therapeutic index, sustained-release or enteric-coated formulations. - Concomitant administration with anticholinergic drugs e.g. Tiquizium bromide, scopolamine butyl bromide, timepidium bromide, etc. may reduce the action of itopride HCl.

CONTRAINDICATIONS:

Itopride HCl is contraindicated in:

Patients with known hypersensitivity to itopride HCl or any of the excipient of the product. Patient s in whom an increase in gastrointestinal motility could be harmful e.g., gastrointestinal hemorrhage, mechanical obstruction or perforation.

OVERDOSAGE:

There have been no reported cases of overdose in humans. In case of excessive overdose, the usual measures of gastric lavage and symptomatic therapy should be applied.

STORAGE & INSTRUCTIONS:

Store between 15-25°C.

Protect from heat, sunlight and moisture.

Keep away from the reach of children.

To be sold on the prescription of a registered medical practitioner only.

HOW SUPPLIED:

ITOSEL Tablet 50mg

10's tablets.

خوراک وطریقہ استعمال:

ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:

دوا کو ۱۵-۲۵ ڈگری سینٹی گریڈ درجہ حرارت کے درمیان رکھیں۔

دھوپ، گرمی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

Manufactured by:

PHARMASOL

PRIVATE LIMITED

Plot # 549, Sundar Industrial Estate, Lahore, Pakistan.