Ritor 50mg
(Itopride HCl)
Tablets

رائیٹور ۵۰ ملی گرام
ٹیبلٹس

QUALITATIVE AND QUANTITATIVE COMPOSITION
Ritor Tablets 50mg:
Each film-coated tablet contains:
Itopride Hydrochloride……50mg
Innovator's Specs.

DESCRIPTION
Ritor (Itopride hydrochloride) is an orally active Gastroprokinetic agent. Ritor film coated tablets contain 50mg of itopride hydrochloride. The tablet has been formulated to provide immediate release. It is chemically designated as N-[4-[2 (Dimethylamino)ethoxy]benzyl]-3,4-dimethoxybenzamide hydrochloride. Itopride hydrochloride is a substituted benzamide. It has an empirical formula of C H N O -HCl, molecular weight of 20 26 2 4 394.89 g/mol.

CLINICAL PHARMACOLOGY
Mechanism of Action:
Itopride hydrochloride activates gastrointestinal propulsive motility due to its dopamine D2 antagonizing activity and acetylcholinesterase inhibitory activity. Itopride activates acetyl-choline release and inhibits its degradation.
Pharmacodynamics:
• Itopride hydrochloride also has antiemetic action through interaction with D2 receptors located in the chemoreceptor trigger zone.
• Itopride hydrochloride has been shown to accelerate gastric emptying in humans.
• The action of Itopride hydrochloride is highly specific for the upper gastrointestinal tract. Itopride hydrochloride does not affect serum gastrin levels.

Pharmacokinetics:
Absorption: Itopride hydrochloride is rapidly and almost completely absorbed from the gastrointestinal tract. Relative bioavailability is calculated to be 60% due to liver first pass me-tabolism. There is no effect of food on bioavailability. Peak plasma levels (Cmax 0.28 |ig/mL) are reached after 0.5 to 0.75 hours after 50 mg of itopride hydrochloride. Following multiple oral doses ranging from 50 mg to 200 mg tid, itopride hydrochlo-ride and its metabolites showed linear pharmacokinetics over a treatment period of seven days, with minimal accumulation

Distribution:
Approximately 96% of Itopride hydrochloride is bound to plasma proteins. Albumin accounts for most of the binding. Alpha-1 -acid-glycoprotein accounts for less than 15% of binding

Metabolism:
Itopride hydrochloride undergoes extensive hepatic metabolism in humans. Three (3) metabolites have been identified, of which only one exerts minor activity without pharmacological relevance (approximately 2-3% of that of itopride). The primary metabolite in humans is the N-oxide, generated by oxidation of the tertiary amine N-dimethyl group. Ritor is metabolized by a flavin-dependent mono-oxygenase (FMO3). The abundance and efficiency of the human FMO isozymes can be subject to genetic polymorphisms, which can lead to a rare autosomal recessive condition known as trimethylaminuria (fish odor syndrome). The half-life of Itopride hydrochloride may therefore be longer in trimethylaminuria patients. In vivo pharmacokinetic studies on CYP-mediated reactions revealed that Ritor showed neither inhibitory nor inductory effect on CYP2C19 and CYP2E1. CYP content and uridine diphosphate glucuronosyl transferase activity were not altered with the administration of itopride.
Excretion:
Itopride hydrochloride and its metabolites are primarily excreted in the urine. The urinary excretions of Itopride hydrochloride and its N-oxide were 3.7% and 75.4%, respectively, in healthy subjects after oral administration of a single therapeutic dose. The terminal phase half-life of Itopride hydrochloride was approximately six (6) hours.

INDICATIONS AND USAGE
Itopride hydrochloride is used in the treatment of gastrointesti-nal symptoms of • Functional Dyspepsia • Non-Ulcer Dyspepsia (chronic gastritis) i.e., o Sensation of bloating, o Early satiety, o Upper abdominal pain or discomfort, o Anorexia, o Heartburn, o Nausea and o Vomiting

CONTRAINDICATIONS
Itopride hydrochloride is contraindicated in patients with known hypersensitivity to itopride hydrochloride or any of the excipients. Itopride hydrochloride should not be used in patients in whom an increase in gastrointestinal motility could be harmful, e.g. gastrointestinal hemorrhage, mechanical obstruction or perforation.

INTERACTIONS
No interaction was detected when itopride was administered concomitantly with warfarin, diazepam, diclofenac, ticlopidine, nifedipine and nicardipine. Drug-drug interactions that arise due to cytochrome P450 metabolism are not assumed because itopride is metabolised mainly by flavine monooxygenase.
Itopride has gastrokinetic effect that could influence the absorption of concomitantly orally administered medicines. Particular attention should be paid to medicines with a narrow therapeutic index, medicines with prolonged-release of the active substance and enteric-coated drug formulations.
Anticholinergic agents may reduce the action of itopride.
Substances as cimetidine, ranitidine, teprenone and cetrexate do not affect prokinetic activity of itopride.

USE IN SPECIFIC POPULATION

Pregnancy: There are no adequate and well-controlled studies in pregnant women. Therefore, Itopride hydrochloride (Itopride hydrochloride) should not be used during pregnancy unless the benefits outweigh the potential risks. There are no known effects of Ritor on labor or delivery.

Lactation:

Itopride hydrochloride excreted in milk, and because of the potential for adverse reactions in nurs-ing infants, a decision should be made whether to discontinue nursing or to discontin-ue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: Safety of this product in children under the age of 16 has not been established.

Geriatric Use: In general, appropriate caution should be exercised in the administration and monitoring of Itopride hydrochloride in elderly patients reflecting the greater frequency of decreased hepatic, renal function, and of concomitant disease or other drug therapy.

Hepatic & Renal Patients: Itopride is metabolised in liver. Itopride and its metabolites are excreted mainly via kidneys. 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.

PRECAUTIONS:

Itopride potentiates acetylcholine action and can induce side anticholinergic effects. Data about long-term administration of itopride is not available. This medicinal product contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

ADVERSE REACTIONS

The following adverse events have been reported in patients receiving Itopride hydrochloride. Blood and lymphatic system disorders: Leukopenia and thrombocytopenia.

Immune system disorders: Anaphylactoid reaction, Endocrine disorders Increased prolactin level and gynecomas-tia. **Nervous system disorders:** Dizziness, headache and tremor. **Gastrointestinal disorders:** Diarrhea, constipation, abdominal pain, increased saliva and nausea. Hepato-biliary disorders: Jaundice. **Skin and subcutaneous tissue disorders:** Rash, redness, and itching. **Investigations:** Increased AST (SGOT), increased ALT (SGPT), increased gamma-GTP, increased alkaline phosphatase, and increased bilirubin.

DOSAGE AND ADMINISTRATION

The recommended dose of Itopride hydrochloride for adult patients is 150 mg daily [one tablet (50 mg) taken orally three times a day before meals]. The dose may be reduced according to the patient's age and symptoms.

OVERDOSAGE:

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

INSTRUCTIONS

Store below 30°C.
Protect from heat, light and moisture.
Keep all medicines out of the reach of children.
To be sold on the prescription of a registered medical practitioner only

PRESENTATION

Ritor (Itopride Hydrochloride) tablets 50mg are available in ALU/PVC blister pack of 10's.

علامات/طریقہ استعمال

رائیٹور ٹیبلٹس معدے کے علاج کے لئے تجویز کردہ ہے۔

احتیاطی تدابیر:

حاملہ خواتین رائیٹور کے استعمال سے گریز کریں۔ بچوں اور بزرگوں کے لیے رائیٹور ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

مضر اثرات:

چکر آنا، سر کا درد، دست، قبض، پیٹ میں درد، متلی، یرقان، خارش اور کھجلی۔

ہدایات:

خوراک ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
۳۰ ڈگری سینٹی گریڈ سے کم پر رکھیں۔
گرمی، روشنی اور نمی سے محفوظ رکھیں۔
تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔

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