MOSAPRIDE CITRATE

GUTMOVIN®

5 mg Film-Coated Tablet
GASTROPROKINETIC

℞

FORMULATION:
Each film-coated tablet contains:
Mosapride Citrate Dihydrate ..... 5.29 mg
as Mosapride Citrate ..... 5 mg

PRODUCT DESCRIPTION:
A white oblong film-coated tablet engraved "J" on one side and scored line on the other side.

PHARMACODYNAMICS:
Mechanism of action: This drug is a selective 5-HT_4 receptor agonist. It is considered that this drug stimulates 5-HT_4 receptors in the gastrointestinal nerve plexus, which increases the release of acetylcholine, resulting in enhancement of gastrointestinal motility and gastric emptying.

PHARMACOKINETICS:
Plasma concentration: (5 healthy adults under fasting conditions single administration of 5 mg of mosapride citrate)

T_{max} (h)	C_{max} (ng/mL)	$t_{1/2}$ (h)
0.8 ± 0.1	30.7 ± 2.7	2.0 ± 0.2

Means ± standard error:
Plasma Protein Binding Rate: 99.0% [*in-vitro*, human serum, at a concentration of 1 ug/mL, methods of ultrafiltration or equilibrium dialysis].
Main metabolite: des-4-fluorobenzyl compound.
Metabolic pathway: Mosapride citrate is metabolized mainly in the liver, where the 4-fluorobenzyl group is removed, followed by oxidation of the morpholine ring at position 5, and hydroxylation of the benzene ring at position 3.
Excretion route: In urine and feces.
Excretion rate: In urine collected for 48 hours after administration, 0.1% was excreted unchanged compound and 7.0% was excreted as main metabolite (des-4-fluorobenzyl compound). (Healthy adults, single administration of 5 mg of mosapride citrate under fasting conditions).
Metabolic enzyme: Cytochrome P450 sub-family: mainly CYP3A4.

INDICATION:
Mosapride Citrate (Gutmovin) is indicated for the treatment of gastrointestinal symptoms associated with functional dyspepsia, chronic gastritis (heartburn, nausea, vomiting).

DOSAGE AND ADMINISTRATION:
The usual adult dose for oral use is 1 tablet (5 mg of Mosapride citrate) three times a day before or after meals or as prescribed by the physician.

CONTRAINDICATIONS:
Mosapride Citrate (Gutmovin) is contraindicated in the following:
1. Patients with GI hemorrhage, mechanical obstruction, or perforation.
2. Patients with history of hypersensitivity to any of the ingredients of this product. (This product contains lactose and should not be given with patients with rare hereditary problems such as galactose intolerance, lapp-lactase deficiency or glucose galactose malabsorption).

PRECAUTIONS:
Mosapride Citrate (Gutmovin) should not be used in patients for more than 2 weeks if no clinically therapeutic outcome was observed.
When 100 to 330 times the recommended clinical dose (30 to 100 mg/kg/day) of Mosapride Citrate was orally administered to rodents for a long period (104 weeks on rats, 92 weeks on mice), increaased of hepatocellular adenoma and thyroid folicular cell adenoma were observed.

DRUG INTERACTIONS:
Mosapride Citrate (Gutmovin) should be administered with care when co-administered with the following drugs.

Drugs	Signs, Symptoms	Mechanism and Risk Factors
Anticholinergic agents - Atropine sulfate and - Butyl-scopolamine bromide. etc.	There is a possibility that the effect of this drug may be attenuated, Therefore, in case of the concomitant use of the anticholinergic agents, precautions such as taking the drug at intervals should be taken.	A gastroprokinetic effect of this drug is exerted by activation of the cholinergic nerves; concomitant use of anticholinergic agents may decrease the effect of this drug.

ADVERSE DRUG REACTIONS:
The main adverse reactions are diarrhea/loose stools, dry mouth, malaise etc.
Abnormal clinical laboratory test values were also observed. In some cases, which were mainly eosinophilia, elevations of triglyceride, AST (SGOT), ALT (SGPT), ALP and Y-GTP were observed.
Fulminant hepatitis, serious hepatic dysfunction accompanied with marked elevations of AST (SGOT), ALT (SGPT) and Y-GTP, etc. and jaundice may occur and some of them are fatal, the patient should be monitored carefully. If any abnormalities are found, discontinue the administration immediately and give appropriate measures.
Hypersensitivity: Rash, urticaria, occasional edema.
Hematological: Occasional eosinophilia, leukopenia.
Gastrointestinal: Abdominal distension, oral paralysis (tongue and lip), occasional diarrhea, loose stools, dry mouth, nausea, vomiting, taste abnormality.
Hepatic: Occasional elevation of ALP, elevation of bilirubin.
Cardiovascular: Occasional palpitation.
Psychoneurological: Occasional dizziness, lightheadedness, headache.
Others: Tremor, elevations of triglyceride.

USE IN ELDERLY PATIENTS:
Since in the elderly patients, their physiological function in the kidneys and the liver are reduced in general, this drug should be administered with care by monitoring patient's condition. If any adverse reactions are found, appropriate measures such as reducing the dose (e.g., to 7.5 mg daily) should be given.

USE IN PEDIATRIC PATIENTS:
Safety of this drug in children has not been established.

PREGNANCY AND LACTATION:
This drug should be used in pregnant women, women who may possibly be pregnant, only if the expected therapeutic benefits outweigh the possible risks associated with the treatment. [Safety of this drug in pregnant women has not been established.]
Administration of this drug to nursing mothers should be avoided. If administration is essential, nursing mothers should discontinue breastfeeding during the treatment.

OVERDOSAGE:
Since data regarding overdosage with this medication is limited, medical attention should be sought for any overdosage.

CAUTION:
Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

For suspected adverse drug reaction, consult your doctor immediately. Report to JustRight Healthcare Inc. at justright_healthcare@outlook.com and to FDA at www.fda.gov.ph.

STORAGE CONDITION:
Store at temperatures not exceeding 30°C.

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.

AVAILABILITY:
Alu/Clear PVC Blister Pack x 10's (Box of 100's)

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Manufactured by:
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