MOSID MT

(Mosapride Citrate Tablets, 2.5, 5 or 10 mg)

COMPOSITION

MOSID MT 2.5

Each uncoated tablet contains :

Mosapride Citrate dihydrate equivalent to Mosapride Citrate anhydrous 2.5 mg.

MOSID MT 5

Each uncoated tablet contains :

Mosapride Citrate dihydrate equivalent to Mosapride Citrate anhydrous 5 mg.

MOSID MT 10

Each uncoated tablet contains :

Mosapride Citrate dihydrate equivalent to Mosapride Citrate anhydrous 10 mg.

PROPERTIES

Mosapride is an upper GI tract prokinetic agent with a selective $5HT_4$ receptor agonist action.

PHARMACOLOGICAL PROPERTIES

PHARMACODYNAMICS

The pharmacological profile of Mosapride can be summarized with its three important characteristic.

1) Mosapride is selective 5-HT_4 agonist

2) Mosapride stimulates upper gastrointestinal motility

3) Mosapride is devoid of dopamine D_2 receptor antagonist property.

It is believed 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. In addition, the principle metabolite (M1) has a high affinity for 5-HT_3 receptors and has proved to be a potent 5-HT_3 antagonist. Because of its 5-HT_4 agonistic and 5-HT_3 antagonistic actions, Mosapride enhances gastric emptying, increases gastric and duodenal motility, but does not increase colonic motility. Together with this action, it has a potential to act as an antiemetic agent. Mosapride 5mg three times a day improved heartburn and vomiting associated with chronic gastritis, in a double blind, comparative clinical trial involving 435 patients (Miyoshi A et al., Rinsho Iyaku, 14, 1037, 1998). In another study Mosapride 40 mg q.d.s. was shown to be effective in decreasing acid reflux in the esophagus in patients with GERD (Aliment Pharmacol Ther 1998; 12 : 35-40).

PHARMACOKINETICS

Absorption

After oral administration Mosapride is rapidly absorbed and achieves its maximum concentration at 0.8 hrs. The maximum concentration after administration of 5 mg Mosapride tablet to fasting healthy volunteers was 30.7 ng/ml. The elimination half life (t½) observed in healthy volunteers was 2 hrs.

Distribution

Mosapride has very high protein binding capacity. It is 99.0 % bound to plasma proteins after oral administration.

Metabolism

Mosapride citrate is metabolized mainly in the liver, where the 4-fluorobenzyl group is removed, which is followed by oxidation of the morpholine ring at position 5, and hydroxylation of the benzene ring at position 3. The major metabolic enzyme involved is cytochrome P450-3A4. The main metabolite of Mosapride, des-4-fluorobenzyl compound is a 5-HT_3 antagonist.

Excretion

0.1% of Mosapride is excreted as unchanged drug and 7.0% as the main metabolite is excreted in urine after 48 hrs in healthy volunteers. It is also excreted in feces.

Mean pharmacokinetic parameters of Mosapride in man following single oral administration at doses of 5 and 10mg of Mosapride.

Dose mg	Mean ± SD						
	Cmax (ng/ ml)	Tmax (h)	T½ (h)	AUC (ng.h/ml)	CL/F (l/h)	Vd/F (l/kg)	MRT (h)
5	30.7±2.7	0.8±0.1	2.0±0.2	67±8	80±11.5	3.5±0.3	2.7±0.3.
10	63.6±13.5	0.8±0.1	1.9±0.1	170±22	62.6±7.5	2.8±0.4	3.2±0.2

Source : American-forsch/ Drug Res.43(II), Nr.8 (1933)

INDICATIONS

MOSID MT is indicated in the treatment of gastroesophageal reflux disorder (GERD) and gastrointestinal symptoms (heartburn/vomiting) associated with chronic gastritis.

USE IN SPECIAL POPULATION

Geriatric

As elderly patients often have reduced physiological function in the kidneys and the liver, careful evaluation of the patients' condition is recommended. In case of adverse reaction, appropriate measures such as reducing the dose should be taken.

Pregnancy and Lactation

The safety of this drug in pregnant women and nursing mothers has not been established. Therefore, in pregnant women, women who may possibly be pregnant, and nursing mother, this drug should be used only if the expected therapeutic benefits outweigh the possible risks associated with treatment. In studies in rats the drug has been shown to be excreted in breast milk. Therefore, administration of this drug to nursing mothers should be avoided. If administration is necessary, nursing mothers should discontinue breast-feeding during treatment.

Pediatric

Safety of this drug in children has not been established.

ADVERSE REACTIONS

In different clinical trials, adverse reactions were observed in 40 (4.0%) out of 998 patients. The main adverse reactions were diarrhea/loose stools (1.8%), dry mouth (0.5%), malaise (0.3%), etc. Abnormal laboratory values were observed in 30 (3.8%) of 792 cases and included increased eosinophils (1.1%), triglycerides (1.0%), SGOT, SGPT, ALP and □-GTP (0.4% each).

Commonly observed adverse events in Mosapride clinical trials are summarized below.

Body system	Adverse effects
Gastrointestinal	Diarrhea/ loose stools, dry mouth, abdominal pain
Hepatic	Increased SGOT, SGPT, ALP, □-GTP
Cardiovascular	Palpitation
Others	Malaise, dizziness/ light-headed feeling, eosinophilia, increased triglycerides

DRUG INTERACTIONS

Drugs	Signs, Symptoms	Treatment Mechanism and Risk Factors
Anticholinergic agent : Atropine sulfate Butylscoporamine Bromide	Since the concomitant use of anticholinergic agents may decrease the effect of this drug, precautions such as taking the drugs at intervals should be taken.	As the gastroprokinetic effect of this drug is exerted by activation of the cholinergic nerves, the concomitant use of decrease the effect of this drug.

The gastric emptying enhancing effect of Mosapride is antagonized by atropine, but not by naloxone, methysergide, propranolol, ritanserin, pyrilamine, indomethacin, phenoxybenzamine, yohimbine or bicuculline. No drug interactions have been observed between Mosapride and the anti-ulcer agents like cimetidine, famotidine and omeprazole.

DOSAGE AND ADMINISTRATION

For adults

The usual dose of MOSID MT is 5 mg three times daily before or after meals; can be increased to not more than 40 mg/day.

DIRECTION FOR USE

MOSID MT tablet dissolves rapidly in mouth and therefore can be taken with or without water.

OVERDOSE

No information on over dosage of Mosapride in humans is available currently.

EXPIRY DATE

Do not use later than the date of expiry

STORAGE

STORE BELOW 30^{0}C, PROTECTED FROM MOISTURE.

Keep medications out of reach of children

PRESENTATION

MOSID MT 2.5-It is available as white to off-white colored, round, flat uncoated tablet in strip of 10 tablets.

MOSID MT 5-It is available as peach colored, round, flat uncoated tablet in strip of 10 tablets.

MOSID MT 10-It is available as peach colored, round, flat uncoated tablet in strip of 10 tablets.

torrent PHARMA

Manufactured by :

TORRENT PHARMACEUTICALS LTD.

Baddi 173 205, Dist. Solan (H.P.) INDIA.