

Generic name

Mosapride citrate

Pharmaceutical form

Film coated tablet

Composition

Each film coated tablet:

Active ingredient:

Mosapride citrate 2.5 mg

Mosapride citrate 5 mg

Inactive ingredient:

Lactose monohydrate, microcrystalline cellulose, magnesium stearate, povidone, colloidal silicon dioxide, Talc (purified), crosscarmellose sodium.

Pharmacodynamic action

- Mosapride table stimulates serotonin receptors in the digestive tract and increases acetylcholine release in order to improve the function of enterokinase and gastric emptying.
- Mosapride is a selective 5-HT₄ receptor agonist with no affinity to 5-HT₁ - 5-HT₂.
- Mosapride improves esophageal motility for patient with (GERD).
- Mosapride increases esophageal bolus transit.
- Mosapride shortens gastric emptying time.
- Mosapride reduces acid reflux variables (assessed using ambulatory pH monitoring).

Pharmacokinetics

- After oral administration of single dose of Mosapride 5 - 40 mg, peak Mosapride concentration (C_{max}) was reached after ~1 hour. Mean elimination half-lives (t) were 1.4 - 2.0 hours.
- Plasma C_{max} (52.0 ng/ml) of the active M 1 metabolite occurred 0.5 hours after a single dose of mosapride 40 mg. Elimination of M 1 (t = 4.3 hours).
- Mosapride is excreted in urine and feaces in 48 hours after administration of a single dose of Mosapride 5 mg.

Indications

- Heartburn, nausea, and vomiting caused by chronic gastritis.
- As adjuvant therapy with orally gastrointestinal lavage solution for barium enema x-ray examination.

Dosage and administration

- General dosage regimen: The recommended usual dosage of Mosapride for adults is 5 mg three times daily before or after meals.
- Missed dosage: Take the missed dose as soon as possible. However, if it is almost time for the next dose, skip the missing dose and continue your regular dosing schedule.
- Overdose: is you took much of this medicine (more than advised), check with your doctor.
- Other: Do not stop taking this medicine without doctors instructions.

Contraindications

- Hypersensitivity to Mosapride or any of the components.

- Patients with hemorrhage or digestive blockage.

Side effects

- No serious adverse events were reported, however in only 2.71% of patients who had received mosapride for more than 2 weeks show abdominal pain, diarrhea, dry mouth, loose stool, rash, hives, nausea and feeling fullness, generalized fatigability and loss of appetite.

- Elevated triglycerides in 1.0% of patients and elevated AST, ALT and GGT in 1.4% of patients may occur.

- Rarely ventricular tachycardia may occur in patient with hypokalaemia.

- Jaundice, liver dysfunction and fulminating hepatitis may rarely occur.

Drug interactions

- Concurrent use with anti-cholinergic agents (atropine, butylscopolamine bromide) decreases Mosapride action.

- Concurrent use with (ketoconazole, itraconazole, macrolide antibiotics, HIV protease inhibitors) may increase plasma concentration of Mosapride.

Pregnancy and lactation

Not be used in pregnancy and lactation.

Storage condition

- Store in dry place at Temperature not exceeding 30C.

- Keep out of reach of children.

- Discard the remainder. Do not store.

Package

Cartoon box containing 1.2.3 (Al/PVC) blisters each of 10 tablets and inner leaflet.

Patient information

Not to be used without physician instructions.