Famotid
Suspension

DRUG INTERNATIONAL LTD.

Composition : Famotid Suspension : Each 5ml reconstituted suspension contains Famotidine USP 40mg.

Pharmacology : Famotidine is a H2-receptor antagonist. By inhibiting H2 receptor it inhibits the secretion of gastric acid, reducing both the volume of the acid and pepsin content of the secretion. Famotidine has a relatively long duration of action and a single 40mg/5ml dose effectively suppresses gastric acid secretion for twelve hours.

Indication : Famotidine is indicated in Duodenal ulcer, Gastric ulcer, Gastroesophageal reflux disease, acute stress ulcer and Zollinger-Ellison syndrome. It is also indicated in acute gastritis, chronic gastritis in acute exacerbation stage.

Dosage and administration :

Gastroesophageal Reflux Disease(GERD):

<1 year of age: 0.5 mg/kg/dose of famotidine oral suspension up to 8 weeks once daily in patients

Age 3 to 11 months: 0.5 mg/kg/dose twice daily up to 8 weeks

Age 1 to 2 months: 0.5 mg/kg/dose once daily up to 8 weeks

Neonates: 0.5 mg/kg/dose maximum once daily up to 8 weeks

Patients 1-16 years of age:

Gastroesophageal Reflux Disease (GERD): 1 mg/kg/day p.o. divided b.i.d. up to 40 mg b.i.d.

Duodonal ulcer: 0.5 mg/kg/day p.o. at bedtime or divided b.i.d. up to 40 mg/day.

Peptic ulcer: 0.5 mg/kg/day p.o. at bedtime or divided b.i.d. up to 40 mg/day.

Maintenance therapy: 40 mg at daily night.

Reflux esophagitis: 2 mg/kg/day

Zollinger-Ellison Syndrome: 40 mg 3 times daily. Or, as directed by a registered physician.

Side effects : Adverse effects of Famotidine are generally infrequent and minor and rash may occur, Headache, dizziness, constipation and diarrhea have been reported rarely. Other side-effects, reported even less frequently, included dry mouth, nausea and /or vomiting abdominal discomfort, anorexia, fatigue, rash during Famotidine therapy.

Contraindication : Famotidine is contraindicated for patients who have hypersensitivity to the drug or any other ingredients.

Precaution : CNS adverse effects have been reported in patients with moderate and severe renal insufficiency, longer intervals between doses or lower doses may need to be used in patients with moderate creatinine clearance.

Pregnancy and Lactation : Pregnancy category B. There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed. Caution should be exercised when Famotidine is administered to a nursing woman.

Drug Interaction : No clinically important drug interactions have been identified. Famotidine does not interact with the cytochrome P450-linked drug metabolizing enzyme system.

Overdose : There is no data available.

Storage : Store below 30°C in a dry place. Protect from light. Keep out of reach of the children.

Packing : Famotid Suspension : Each bottle contains dry powder for preparation of 50ml suspension.