FAMOTIDINE TABLET

eVIFAM02-1 (SIN)

DESCRIPTION
Famotidine 20 mg and 40 mg Tablet: Square, light orange film-coated tablet, bevel-edged with shallow convex faces.

COMPOSITION
Famotidine 20 mg/tablet
Famotidine 40 mg/tablet

ACTION & PHARMACOLOGY
Famotidine is a H_2-receptor antagonist. It inhibits basal and nocturnal gastric acid secretion by competitive inhibition of the action of histamine at the histamine H_2-receptors of the parietal cells. It also inhibits gastric acid secretion stimulated by food, betazole, pentagastrin, caffeine, insulin and physiological vagal reflex. It is rapidly but incompletely absorbed from the gastro-intestinal tract. Most is excreted unchanged in urine.

INDICATIONS
Famotidine is indicated in the short term treatment of duodenal ulcer, benign gastric ulcer and hypersecretory conditions such as Zollinger-Ellison syndrome. It is also used in the prevention of relapses of duodenal ulceration, symptomatic relief of gastro-oesophageal reflux disease and healing of oesophageal erosions or ulceration associated with gastro-oesophageal reflux disease.

CONTRAINDICATIONS
Risk-benefit should be considered when the following medical problems exist:
- Cirrhosis
- Hepatic and renal function impairment
- Sensitivity to any of the histamine H_2-receptor antagonists

PRECAUTIONS
Patients with moderate or severe renal insufficiency: Since 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 < 50mL/min) or severe (creatinine clearance < 10mL/min) renal insufficiency to adjust for the longer elimination half-life of famotidine.

Patients with Gastric Ulcer: Before giving famotidine to patients with gastric ulcers, the possibility of malignancy should be excluded since famotidine may mask symptoms and delay diagnosis. It should be given in reduced dosage to patients with impaired renal function.

Pregnancy and Lactation: It is not recommended for use in pregnancy and should be prescribed only if clearly needed and the physician should again weigh the potential benefits from the drug against the possible risks. Famotidine is secreted in human milk, therefore breast-feeding mothers should either stop breast-feeding or stop taking the drug.

Paediatric use: Safety and effectiveness of famotidine in children have not been established.

Geriatric use: As elderly patients are more likely to have decreased clearance of famotidine, care should be taken in dose selection and it may be useful to monitor renal function.

MAIN SIDE/ADVERSE EFFECTS
Headache, drowsiness, nausea and vomiting, loss of appetite, diarrhoea, constipation, dryness of mouth and skin, skin rash, loss of hair, joint or muscle pain, ringing or buzzing in ears and confusion. Famotidine is reported to have little or no anti-androgenic effects, although there are isolated reports of gynaecomastia and impotence.

OVERDOSAGE
Clinical features: Experience with overdose in humans is limited. Toxic doses of famotidine given intravenously to dogs caused emesis, restlessness, pallor of mucous membranes or redness of mouth and ears, skin rash.

Treatment: Since there is no specific antidote for overdose, treatment is symptomatic and supportive with possible utilization of the following:
- Induction of emesis and/or use of gastric lavage.
- For seizures, treatment with intravenous diazepam.
- For bradycardia, treatment with atropine.
- For ventricular arrhythmias, treatment with lidocaine.
- Possible laboratory monitoring for adverse reactions.

DRUG INTERACTIONS
- Clinical experience with famotidine is very limited.
- Simultaneous administration of antacids is not recommended since absorption of famotidine may be decreased; patients should be advised not to take any antacids within ½ to 1 hour of histamine H_2-receptor antagonists.
- Concurrent use with bone marrow depressants may increase the risk of neutropenia or other blood dyscrasias.
- Concurrent administration of ketoconazole may result in a marked reduction in absorption of ketoconazole; patients should be advised to take famotidine at least 2 hours after ketoconazole.

DOSAGE & ADMINISTRATION
Usual adult and adolescent dose:
Duodenal ulcer: Oral, 40 mg once daily at bedtime or 20 mg 2 times daily.
Prophylaxis of recurrent duodenal ulcer: Oral, 20 mg at bedtime.
Gastric ulcer: Oral, 40 mg once daily at bedtime.
Gastric hypersecretory conditions (eg. Zollinger-Ellison syndrome): Oral, 20 mg every 6 hours, the dosage being adjusted as needed and therapy continued for as long as clinically indicated. Doses up to 160 mg every 6 hours have been administered to some patients with severe Zollinger-Ellison syndrome.
Gastro-oesophageal reflux: Oral, 20 mg 2 times daily for up to 6 weeks. The recommended oral dose for oesophagitis due to gastro-oesophageal reflux disease is 20 to 40 mg 2 times daily for up to 12 weeks.
Dosage Adjustment for patients with moderate to severe renal insufficiency: In adult patients with moderate (creatinine clearance < 50 mL/min) or severe (creatinine clearance < 10mL/min) renal insufficiency, the dose of Famotidine may be reduced to half the dose or the dosing interval may be prolonged to 36-48 hours as indicated by patient's clinical response.

Note: The information given here is limited. For further information, please consult your doctor or pharmacist.

Storage: Store below 25°C. Protect from light and moisture.

Shelf-life: 3 years from date of manufacture.

Presentation/Packing:
Film-coated tablet 20 mg x 1000's, Blisters of 10 x 10's, 100 x 10's
Film-coated tablet 40 mg x 1000's, Blisters of 10 x 10's
(Not all presentations may be available locally)

Manufactured / Batch Released by: HOVID Bhd.
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