



Famotack[®]

Famotidine
Antiulcerants

COMPOSITION

Famotack[®] 20 mg tablet : Each film coated tablet contains Famotidine USP 20 mg.

Famotack[®] 40 mg tablet : Each film coated tablet contains Famotidine USP 40 mg.

PHARMACOLOGY

Famotack[®] (Famotidine) is a histamine H₂-receptor antagonist. Famotack[®] completely inhibits the action of histamine on H₂-receptors of parietal cell. It inhibits basal, overnight and pentagastrin stimulated gastric acid secretion. The H₂-receptor antagonist activity of Famotack[®] is slowly reversible, since the drug dissociates slowly from H₂-receptor.

Peak plasma concentrations of 50-60 µgm Famotidine/L are attained with 1 to 3½ hours after a 20 mg oral dose ; a concentration of 13 µgm/L is required for 50% inhibition of stimulated secretion of gastric acid.

The drug appears to have minimal effect on fasting and postprandial serum gastrin concentration. Famotidine does not appear to affect gastric emptying, lower esophagus sphincter pressure or biliary secretion. Food or antacid does not interfere its absorption. The elimination half-life of Famotack[®] is 2.5 - 4 hours in average in adults with normal renal function. Famotack[®] is metabolized in the liver to famotidine-s-oxide. The metabolite does not appear to inhibit gastric acid secretion. It is excreted principally in urine via glomerular filtration and tubular secretion. The drug is 15-20% protein bound.

INDICATION

Famotack[®] tablet is indicated in Duodenal ulcer, Gastric ulcer, Gastro-oesophageal 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

Duodenal ulcer. The recommended initial dose is one tablet of Famotack[®] 40 at night. Alternatively Famotack[®] 20 twice daily may be administered orally in adults. In most patients healing occur within 4 to 8 weeks.

Maintenance therapy. For preventing the recurrence of duodenal ulceration the reduced dose is Famotack[®] 20 one tablet at night.

Famotack®

Benign gastric ulcer: The recommended dose is one tablet Famotack® 40 at night. Treatment should continue unless endoscopy reveals healing.

Zollinger-Ellison syndrome: Patients without prior antisecretory therapy, should receive Famotack® 20 every 6 hours. Dosage should then be adjusted to individual response.

Gastro-esophageal reflux: Famotack® 20 twice daily for 6 to 12 weeks.

Doses up to 160 mg every six hours have been administered to some patients without the development of significant adverse effects. Dosage can be administered irrespective of meals.

CONTRAINDICATION AND PRECAUTION

Hypersensitivity to famotidine or any component of the formulation. Safety and effectiveness of the drug in children have not yet been established.

SIDE EFFECT

In controlled studies, Famotack® has been shown to be generally well tolerated. Headache, dizziness, constipation and diarrhoea have been reported rarely. Other side-effects, reported even less frequently, included dry mouth, nausea and/or vomiting, abdominal discomfort or distention, anorexia, fatigue, rash.

DRUG INTERACTION

No clinically important drug interactions have been identified. Famotack® does not interact with the cytochrome P₄₅₀-linked drug metabolising enzyme system.

USE IN PREGNANCY AND LACTATION

There are no adequate, well-controlled studies of Famotidine in pregnancy, but it is known to cross the placenta and should be prescribed only if clearly needed. The drug is known to be secreted in human milk; it is best avoided by nursing mothers.

STORAGE CONDITION

Store in a dry and cool place, keep away from sunlight.

HOW SUPPLIED

Famotack® 20 tablet : Box containing 10 x 10 tablets in blister pack.

Famotack® 40 tablet : Box containing 5 x 10 tablets in blister pack.

