W=100 mm

Famodin®

Tablet/ Powder for Suspension

Famotidine USP

COMPOSITION
Famodin® 20 : Each film-coated tablet contains Famotidine USP 20 mg.
Famodin® 40 : Each film-coated tablet contains Famotidine USP 40 mg.
Famodin® Powder for Suspension : After reconstitution each 5 ml suspension contains Famotidine USP 40 mg.

PHARMACOLOGY
Famodin® (Famotidine) is a H_2 receptor antagonist. Famotidine lowers the excess acid secretion by blocking the histamine (H_2) receptor and thus accelerates ulcer healing process of stomach. Famotidine suppresses stimulated acid output within two hours after administration for 12 hours. The affinity of Famotidine for the H_2 receptor is significantly greater than those of Ranitidine or Cimetidine. Famotidine has no anti-androgenic activity and has no action on hepatic cytochrome P450 activity.

INDICATIONS
Famodin® is indicated in duodenal ulcer, gastric ulcer, prophylaxis of duodenal ulcer relapse, gastroesophageal reflux disease, zollinger-ellison syndrome.

DOSAGE AND ADMINISTRATION
Route of administration : Orally.
Adult Dose :
In gastric and duodenal ulcer: Famodin® 40 mg at night.
Duodenal ulcer: The recommended initial dose is 40 mg Famodin® at night. Treatment should be continued for four to eight weeks. In most patients, healing occurs on this regimen within four weeks. In those patients whose ulcers have not healed completely after four weeks, a further four week period of treatment is recommended.
Maintenance therapy: For preventing the recurrence of duodenal ulceration, the reduced dose of 20 mg Famodin® at night is recommended. This 20 mg maintenance dose has been continued effectively in clinical studies for 12 months.
Gastric ulcer: The recommended dose is 40 mg Famodin® at night. Treatment should be continued for four to eight weeks unless endoscopy reveals earlier healing.
Gastroesophageal Reflux Disease (GERD):
Symptomatic: 20 mg b.i.d
Erosive: 40 mg b.i.d
Maintenance dose: 20 mg b.i.d
Zollinger-Ellison Syndrome: Patients without prior antisecretory therapy should be started on 20 mg Famodin® every six hours. Dosage should then be adjusted to individual response. Dosage up to 480 mg daily in divided doses have been used up to one year without the development of significant adverse effects. Patients who have been receiving another H_2-antagonist may be switched directly to Famodin® at a dose higher than that recommended few cases. The starting dose will depend on the severity of the condition and the last dose of H_2-antagonist previously used.
Dosage adjustment in renal impairment : Since Famodin® is excreted primarily by the kidney; caution should be observed in patients with impaired renal function. A reduction in daily doses should be considered if creatinine clearance falls to or below 30 ml/min, then dose should be reduced in 20 mg per day.
Child Dose :
Gastroesophageal Reflux Disease (GERD):
Less than 3 months : 0.5 mg/kg once daily for up to 8 weeks.
3 months to less than 1 years : 0.5 mg/kg orally 2 times a day for up to 8 weeks.
1 year to 16 years : 1 mg/kg/day orally 2 times a day.
Maximum dose : Up to 40 mg/dose.
Dyspepsia : 0.5 mg/kg orally once daily.
Peptic ulcer : 0.5 mg/kg orally once daily or divided in twice daily up to 40 mg/day.

Dosage can be administered irrespective of meals. Antacids may be given concomitantly if needed.
OR AS DIRECTED BY THE PHYSICIAN.

CONTRAINDICATIONS
This drug is contraindicated in patients hypersensitive to Famotidine.

PRECAUTIONS
Caution should be exercised when prescribing Famodin® to patient with kidney disease. This drug may be used during pregnancy and for nursing mother, only if needed.

SIDE EFFECTS
Common side effect : Headache, dizziness, constipation, diarrhoea, dryness of mouth, nausea, skin rash, intestinal disturbance, anorexia and fatigue are the most common side effects.
Rare side effect : Impotence and gynecomastia.

USE IN PREGNANCY & LACTATION
Pregnancy : Pregnancy Category B. There is no adequate or well-controlled studies in pregnant women but potential benefits may warrant use of the durg in pregnant women despite potential risks.
Lactation : Famotidine is detectable in human breast milk. Decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

USE IN CHILDREN & ADOLESCENTS
Safe for use in children and adolescents.

DRUG INTERACTION
With Medicine : Antacids slightly decreases the bioavailability of Famotidine. May reduce serum concentration of ketoconazole and itraconazole.
With food & others : Avoid Alcohol and limit Caffaine intake.

OVERDOSE
There have been no reports of serious illness effects from over dose of Famotidine rather it can show fever, asthenia, fatigue.

STORAGE
Store below 30^0 C temperature and dry place, Protected from light.
Keep all medicines out of reach of children.

PACKING
Famodin® 20 : Each box contains 10 X 15 tablets in blister strips.
Famodin® 40 : Each box contains 6 X 15 tablets in blister strips.
Famodin® Powder for Suspension : Each box contains sealed cap bottle containing dry powder for reconstituting 60 ml suspension with a measuring cup and a dropper.

*** Further information is available on request.**

Manufactured by:
The ACME Laboratories Ltd.
Dhulivita, Dhamrai, Dhaka, Bangladesh
For Health, Vigour and Happiness

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