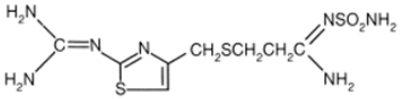
Pepcidine® Tablets
(Famotidine)

پیپسیڈین ٹیبلیٹس

QUALITATIVE & QUANTITATIVE COMPOSITION
Each film-coated tablet contains:
Famotidine U.S.P. .....40 mg.

DESCRIPTION
The active ingredient in Pepcidine is famotidine, a histamine H2 - receptor antagonist. Famotidine is N (aminosulfonyl) - 3 - [[[2 - [(diaminomethylene) amino] - 4 - thiazolyl] methyl]thio] propanimidamide. The empirical formula of famotidine is $C_8H_{15}N_7O_2S_3$ and its molecular weight is 337.43. Its structural formula is:



CLINICAL INFORMATION
Indications
Pepcidine (Famotidine) tablets are indicated in adult and pediatric patients 40 kg and greater for the treatment of:
- Active duodenal ulcer (DU).
- Active gastric ulcer (GU).
- Symptomatic nonerosive gastroesophageal reflux disease (GERD).
- Erosive esophagitis due to GERD, diagnosed by biopsy.

Pepcidine (Famotidine) tablets are indicated in adults for the:
- Treatment of pathological hypersecretory conditions (e.g., Zollinger-Ellison syndrome, multiple endocrine neoplasias).
- Reduction of the risk of duodenal ulcer recurrence.

Dosage and Administration
Table 1: Recommended Dosage and Duration of Pepcidine (Famotidine) Tablets in Adult and Pediatric Patients 40 kg and Greater with Normal Renal Function

Indication	***Recommended Dosage***	***Recommended Duration***
Active duodenal ulcer (DU)	40 mg once daily; or 20 mg twice daily	Up to 8 weeks
Active gastric ulcer	40 mg once daily	Up to 8 weeks
Symptomatic nonerosive GERD	20 mg twice daily	Up to 6 weeks
Erosive esophagitis diagnosed by endoscopy	20 mg twice daily; or 40 mg twice daily	Up to 12 weeks
Pathological hypersecretory conditions	Starting dosage: 20 mg every 6 hours; adjust dosage to individual patient needs Maximum dosage 160 mg every 6 hours	As clinically indicated
Reduction of the risk of DU recurrence	20 mg once daily	1 year or as clinically indicated

Table 2: Recommended Maximum Dosage of Pepcidine (Famotidine) Tablets in Adult and Pediatric Patients 40 kg and Greater with Moderate and Severe Renal Impairment

Indication	**Recommended Maximum Dosages**	
	Creatinine clearance 30 to 60 mL/minute	**Creatinine clearance less than 30 mL/minute**
Active duodenal ulcer (DU)	20 mg once daily; or 40 mg every other day	20mg every other day
Active gastric ulcer	20 mg once daily; or 40 mg every other day	20mg every other day
Symptomatic nonerosive GERD	20 mg once daily	20mg every other day
Erosive esophagitis diagnosed by endoscopy	20 mg once daily; or 40 mg every other day	20mg every other day
	40 mg once daily	20mg once daily
Pathological hypersecretory conditions	Avoid Use	
Reduction of the risk of DU recurrence	20mg every other day	10 mg every other day. Since 20 mg or 40 mg tablet strength cannot be used for this dosage regimen, use an alternate famotidine formulation

- Pepcidine (Famotidine) may be taken with or without food.
- Pepcidine (Famotidine) may be given with antacids.

Contraindications
Pepcidine (Famotidine) is contraindicated in patients with a history of serious hypersensitivity reactions (e.g., anaphylaxis) to famotidine or other histamine-2 (H2) receptor antagonists.

Warnings and Precautions
- *Central Nervous System Adverse Reactions* - Central nervous system (CNS) adverse reactions, including confusion, delirium, hallucinations, disorientation, agitation, seizures, and lethargy may occur in elderly patients and patients with moderate and severe renal impairment treated with Pepcidine (Famotidine). Since famotidine blood levels are higher in patients with renal impairment than in patients with normal renal function, dosage adjustments are recommended in patients with renal impairment

- *Concurrent Gastric Malignancy* - In adults, symptomatic response to therapy with Pepcidine (Famotidine) does not preclude the presence of gastric malignancy. Consider evaluation for gastric malignancy in adult patients who have a suboptimal response or an early symptomatic relapse after completing treatment with Pepcidine (Famotidine).

Interactions
- *Drugs Dependent on Gastric pH for Absorption* - Pepcidine (Famotidine) can reduce the absorption of other drugs, due to its effect on reducing intragastric acidity, leading to loss of efficacy of the concomitant drug. Concomitant administration of Pepcidine (Famotidine) with dasatinib, delavirdine mesylate, cefditoren, and fosamprenavir is not recommended. Other drugs dependent on gastric pH for absorption for administration, including atazanavir, erlotinib, ketoconazole, itraconazole, ledipasvir/sofosbuvir, nilotinib, and rilpivirine.
- *Tizanidine (CYP1A2 Substrate)* - Pepcidine (Famotidine) is considered a weak CYP1A2 inhibitor and may lead to substantial increases in blood concentrations of tizanidine, a CYP1A2 substrate. Avoid concomitant use with Pepcidine (Famotidine). If concomitant use is necessary, monitor for hypotension, bradycardia or excessive drowsiness.

Pregnancy and Breast Feeding

Pregnancy

Category B

Available data with H2-receptor antagonists, including Pepcidine (Famotidine), in pregnant women are insufficient to establish a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. The recommended human dose of 80 mg per day for the treatment of erosive esophagitis.

The estimated background risk for major birth defects and miscarriage for the indicated population is unknown.

Nursing Mothers

There are no data on Pepcidine (Famotidine) effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for famotidine and any potential adverse effects on the breastfed child from Pepcidine (Famotidine) or from the underlying maternal condition.

Pediatric Use

The safety and effectiveness of Pepcidine (Famotidine) have been established in pediatric patients for the treatment of peptic ulcer disease (i.e., duodenal ulcer, gastric ulcer) and GERD (i.e., symptomatic nonerosive GERD, erosive esophagitis as diagnosed by endoscopy). Pepcidine (Famotidine) 40 mg tablets are not recommended for use in pediatric patients weighing less than 40 kg because these tablet strengths exceed the recommended dose for these patients

Elderly

Use the lowest effective dose of Pepcidine (Famotidine) for an elderly patient and monitor renal function.

Renal Impairment

No dosage adjustment is needed in patients with mild renal impairment (creatinine clearance greater than or equal to 60 mL/minute). Dosage reduction is recommended in adult and pediatric patients greater than or equal to 40 kg with moderate or severe renal impairment (creatinine clearance less than 60 mL/minute). Pepcidine (Famotidine) 20 and 40 mg tablets are not recommended for use in pediatric patients weighing less than 40 kg because these tablet strengths exceed the recommended dose for these patients.

Adverse Reactions

Body as a Whole: Fever, asthenia, fatigue
Cardiovascular: Palpitations.
Gastrointestinal: Elevated liver enzymes, vomiting, nausea, abdominal discomfort, anorexia, dry mouth.
Hematologic: Thrombocytopenia.
Hypersensitivity: Orbital edema, rash, conjunctival injection, bronchospasm.
Musculoskeletal: Musculoskeletal pain, arthralgia.
Nervous System/Psychiatric: Seizure, hallucinations, depression, anxiety, decreased libido, insomnia, somnolence.
Skin: Pruritus, dry skin, flushing.
Special Senses: Tinnitus, taste disorder
Other: Impotence

Over Dosage

In the event of overdosage, treatment should be symptomatic and supportive. Unabsorbed material should be removed from the gastrointestinal tract, the patient should be monitored, and supportive therapy should be employed. Due to low binding to plasma proteins, Pepcidine (Famotidine) is eliminated by hemodialysis.

PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: H2-receptor antagonists; ATC Code: A02BA03

Mechanism of Action

Pepcidine (Famotidine) is a competitive inhibitor of histamine-2 (H2) receptors. The primary clinically important pharmacologic activity of Pepcidine (Famotidine) is inhibition of gastric secretion. Both the acid concentration and volume of gastric secretion are suppressed by Pepcidine (Famotidine), while changes in pepsin secretion are proportional to volume output.

Pharmacokinetics

Absorption

Pepcidine (Famotidine) is incompletely absorbed. The bioavailability of oral doses is 40 to 45%. Bioavailability may be slightly increased by food, or slightly decreased by antacids; however, these effects are of no clinical consequence. Peak Pepcidine (Famotidine) plasma levels occur in 1 to 3 hours.

Distribution

15% to 20% of Pepcidine (Famotidine) in plasma is protein bound.

Metabolism

Pepcidine (Famotidine) undergoes minimal first-pass metabolism. 25% to 30% of an oral dose was recovered in the urine as unchanged compound. The only metabolite identified in humans is the S-oxide.

Excretion

Pepcidine (Famotidine) has an elimination half-life of 2.5-3.5 hours. Pepcidine (Famotidine) is eliminated by renal (65 to 70%) and metabolic (30 to 35%) routes. Renal clearance is 250 to 450 mL/minute, indicating some tubular excretion.

PHARMACEUTICAL INFORMATION

Shelf life

2 Years

Special Precautions for Storage

To be sold on the prescription of a registered medical practitioner only.
Do not store above 30°C.
Protect from light and moisture.
Keep out of the reach of children.

ہدایات:

صرف مستند ڈاکٹر کے نسخے پر فروخت کریں۔
۳۰ ڈگری سینٹی گریڈ سے زیادہ درجۂ حرارت پر نہ رکھیں۔
دوا کو روشنی اور نمی سے بچائیں۔
بچوں کی پہنچ سے دور رکھیں۔

Nature and contents of container

Pepcidine (Famotidine) 40mg tablets are supplied in the blister pack of 10's (1x10's).

MANUFACTURED BY:

ASPIN
An OBS Group Company

Aspin Pharma (Pvt.) Ltd.
Plot No.10 & 25, Sector No. 20,
Korangi Industrial Area Karachi-74900, Pakistan.
www.aspin.com.pk

REVISION DATE

Feburary 2020