VEFAM TABLETS

Famotidine 20 mg and 40 mg
Oral tablets | Pack size: 2 x 10

COMPOSITION

Each Vefam 20 mg tablet contains Famotidine 20 mg. Each Vefam 40 mg tablet contains Famotidine 40 mg. Other ingredients: according to the approved formulation.

THERAPEUTIC CLASS

Histamine H2-receptor antagonist; gastric acid-suppressing and antiulcer agent.

PHARMACOLOGY

Famotidine competitively inhibits histamine H2 receptors on gastric parietal cells, reducing basal and stimulated gastric acid secretion and gastric acid volume.

INDICATIONS

Treatment of active duodenal ulcer, active gastric ulcer, symptomatic nonerosive gastro-oesophageal reflux disease (GERD), and erosive oesophagitis due to GERD. In adults, also used for reducing duodenal ulcer recurrence and treating pathological hypersecretory conditions such as Zollinger-Ellison syndrome, where approved.

DOSAGE AND ADMINISTRATION

Adults with normal renal function: Active duodenal ulcer: 40 mg once daily at bedtime or 20 mg twice daily, for up to 8 weeks. Active gastric ulcer: 40 mg once daily for up to 8 weeks. Symptomatic nonerosive GERD: 20 mg twice daily for up to 6 weeks. Erosive oesophagitis: 20 mg or 40 mg twice daily for up to 12 weeks. Prevention of duodenal ulcer recurrence: 20 mg once daily, when indicated.

HYPERSECRETORY CONDITIONS

For adults with pathological hypersecretory conditions, an initial regimen of 20 mg every 6 hours may be used, adjusted to individual response by a specialist. Higher doses may be required under close medical supervision.

METHOD OF ADMINISTRATION

Take orally with or without food. Once-daily doses are commonly taken at bedtime; twice-daily doses in the morning and at bedtime. Famotidine tablets may be used with antacids if advised. If a dose is missed, take it when remembered unless the next dose is nearly due; do not double.

RENAL IMPAIRMENT

Dose adjustment is required when creatinine clearance is below 60 mL/min. For example, in active ulcer disease with creatinine clearance 30–60 mL/min, a recommended maximum is 20 mg once daily or 40 mg every other day; with clearance below 30 mL/min, 20 mg every other day. Regimens vary by indication; consult the approved renal dosing table. Lower-strength formulations may be necessary.

PAEDIATRIC AND ELDERLY USE

The 20 mg and 40 mg tablets may be used for certain approved indications in paediatric patients weighing at least 40 kg. For children below 40 kg, use a suitable alternative formulation and specialist-directed dose. Older patients are more likely to have reduced renal function; assess kidney function before selecting the dose.

CONTRAINDICATIONS

History of serious hypersensitivity reactions, including anaphylaxis, to famotidine or other histamine H2-receptor antagonists, or any formulation component.

WARNINGS AND PRECAUTIONS

Symptomatic improvement does not exclude gastric malignancy. Investigate alarm symptoms such as gastrointestinal bleeding, unexplained weight loss, persistent vomiting or difficulty swallowing. In moderate or severe renal impairment, accumulation may increase the risk of central nervous system adverse effects and QT prolongation; adjust the dose.

DRUG INTERACTIONS

Famotidine reduces gastric acidity and may reduce absorption of medicines that require an acidic environment, including certain antifungals and some anticancer or antiretroviral agents. Avoid coadministration with tizanidine where recommended by the applicable product label. Review all prescribed and non-prescribed medicines.

PREGNANCY AND LACTATION

Use in pregnancy only when clinically necessary following assessment of benefits and risks. Famotidine passes into human milk. Consider the need for treatment and potential effects on the breastfed infant.

ADVERSE REACTIONS

Common reactions include headache, dizziness, constipation and diarrhoea. Rare serious reactions may include hypersensitivity, confusion or other central nervous system effects (especially with renal impairment), abnormal liver tests, blood disorders and cardiac rhythm disturbances.

OVERDOSAGE

Seek immediate medical advice in case of suspected overdose. Management is supportive and symptomatic; consider renal function and monitor as clinically indicated.

STORAGE

Store in the original packaging under the conditions approved for Vefam. Protect from moisture and keep out of reach of children. Do not use after the expiry date.

PRESENTATION

Vefam Tablets 20 mg: 2 x 10 tablets.
Vefam Tablets 40 mg: 2 x 10 tablets.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.