

PACKAGE LEAFLET

FAMULTRAN

COMPOSITION

Each film-tablet contains: 20 mg Famotidine or 40 mg Famotidine.

ACTION

Famotidine is a fourth generation selective histamine H₂-blocker, several times more potent than ranitidine and particularly more potent than cimetidine. It has practically none of the undesirable effects of the non-selective H₂-blockers. It has a potent and prolonged action which allows its usage in lower doses, administered at longer time intervals.

Famotidine reduces the basal and stimulated secretion of hydrochloric acid in the gastric juice by histamine, gastrin, acetylcholine, caffeine, food, etc. by blocking the H₂-receptors in the parietal cells of the gastric mucosa; it has a certain cytoprotective effect as well. The simultaneous administration of famotidine with food or antacids has no effect on its absorption. The effect after oral administration is manifested in about one hour and lasts for 10-12 hours. A single dose administered in the evening reduces effectively and lastingly the secretion of gastric juice.

INDICATIONS

It is used for the treatment of:

- duodenal ulcer
- active gastric ulcer
- drug, stress and postoperative ulcers

- erosive gastritis and gastroduodenitis
- pathological hypersecretion (Zollinger-Ellison syndrome)
- gastroesophageal reflux.

CONTRAINDICATIONS

Hypersensitivity to famotidine and compounds with a similar structure.

UNDESIRABLE EFFECTS

- The drug is well tolerated by the patients. Undesirable effects occur in 3-7 %.
- Headache, dizziness, constipation, febrile reaction, palpitation, arrhythmia, vomiting, dryness in the mouth, allergic reactions may occur rarely.
- In exceptionally rare cases: arthralgia (painful joints), depression, hallucinations, fear, bronchospasm.

DRUG AND OTHER INTERACTIONS

- Famotidine has no effect on the metabolism of drugs metabolized by the cytochrome P-450 enzyme system.
- The simultaneous administration of **famotidine** and **ketonazole** may reduce the absorption of ketonazole due to the elevated pH in the stomach.
- Food increases the bioavailability of famotidine. Take the drug during meals!

PRECAUTIONS FOR USE

- Prior to starting the treatment, the presence of malignant processes should be ruled out.
- The dose should be reduced for patients with damaged liver and deteriorated renal function.

- FAMULTRAN may be administered to pregnant women only if extremely needed.
- There is no evidence for its excretion with the milk of breast-feeding women, but due to possible risk, the breast feeding or the treatment should be discontinued during the lactation period.
- Due to insufficient evidence, do not administer to children!

There is no evidence for effect on driving ability and machine operation requiring high attention.

USAGE

THIS IS A PRESCRIPTION DRUG!

- ***Duodenal ulcer:*** initially 40 mg every evening, at bed-time during 4 weeks. May be administered 20 mg two times daily. Maintaining dose - 20 mg daily.
- ***Acute gastric ulcer, ulcers caused by medicaments and stress and postoperative ulcers:*** Initially 40 mg daily, every evening at bed-time;
- ***Erosive gastritis and gastroduodenitis*** - 20 mg two times daily;
 - By physician's opinion the dosage and the duration of the treatment may be varied;
 - ***Pathologic hypersecretion*** (syndrome of Zollinger-Ellison)- initially take a dose of 20 mg every 6 hours, and in other patients - higher dose of maximum 160 mg every 6 hours;
 - ***Gastro-oesophageal reflux*** - 20 mg two times daily for 6 weeks. (By physician's opinion the dosage and the duration of the treatment may be varied)

STORAGE

Store in a dry, light-protected place at room temperature (15-25⁰C).

Keep out of reach of children!

SHELF LIFE

Two years.

Do not use the drug after the expiry date, indicated on the package!

FOR ADDITIONAL INFORMATION

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