# FIATFON

**Instructions for the medicinal product**

**Trade name:** Fiatfon.
**International Nonproprietary Name:** Famotidine.
**Dosage form:** Film-coated tablets.
**Composition:**
*Fiatfon 20 mg:* Each film-coated tablet contains:
Famotidine BP 20 mg.
Approved colours used in coating
*Fiatfon 40 mg:* Each film-coated tablet contains:
Famotidine BP 40 mg.
Approved colours used in coating
**Pharmacotherapeutic group:** Histamine H2 receptor antagonist, which inhibits gastric acid secretion.
**ATC Code:** A02BA03.
**Pharmacologic property:**
*Pharmacodynamics:*
Famotidine, a competitive histamine $H_2$-receptor antagonist, is used to treat gastrointestinal disorders such as gastric or duodenal ulcer, gastroesophageal reflux disease, and pathological hypersecretory conditions. Famotidine inhibits many of the isoenzymes of the hepatic CYP450 enzyme system. Other actions of Famotidine include an increase in gastric bacterial flora such as nitrate-reducing organisms.
Famotidine binds competitively to $H_2$-receptors located on the basolateral membrane of the parietal cell, blocking histamine affects. This competitive inhibition results in reduced basal and nocturnal gastric acid secretion and a reduction in gastric volume, acidity, and amount of gastric acid released in response to stimuli including food, caffeine, insulin, betazole, or pentagastrin.
*Pharmacokinetics:*
After oral administration, dose-related peak plasma concentrations are achieved within 1 to 3.5 hours. Mean peak plasma concentrations are between 50 and 60 µg/L after a 20mg oral dose. Plasma concentrations are maintained at this level for about 12 hours after a 40mg oral dose. Bioavailability has been reported to be 40 to 45% and is not dose dependent.
The apparent volume of distribution of famotidine is 1.1 to 1.4 L/kg, but the tissue distribution of famotidine has not been reported. Protein binding is relatively low (15 to 20%).
Famotidine is excreted in the urine, by both glomerular filtration and tubular secretion, and in the faeces. From 25 to 30% of orally administered doses are recovered unchanged in the urine. The elimination half-life of orally administered famotidine is between 2.5 and 3.5 hours in patients with normal renal function, but increases to approximately 20 hours in patients with a creatinine clearance of less than 10 ml/min.
**Indications for use:**
- Peptic ulcer and 12 duodenal ulcer;
- Gastric hyperacidity, heartburn (associated with hyperacidity);
- Symptomatic and stress ulcers of the gastrointestinal tract;
- Erosive reflux esophagitis;
- NSAID-gastropathy;
- Zollinger-Ellison syndrome;
- Systemic mastocytosis;
- Multiple endocrine adenomatosis;
- Prevention of recurrence bleeding in the postoperative period;
- Prophylaxis of aspiration of gastric juice in patients undergoing surgery under general anesthesia (Mendelson's syndrome);
- Aspiration pneumonia (prevention);
- Dyspepsia with epigastric or retrosternal pain, appearing at night or related to food intake.

**Contra-indications:**
- Hypersensitivity to any component of this product;
- Pregnancy and nursing mother (breastfeeding);
- Contraindicated in children.

*Precautions* - hepatic and / or renal failure, liver cirrhosis with port systemic encephalopathy (history), immunodeficiency.
*Pregnancy and Nursing Mother:*
This drug should be used during pregnancy only if clearly needed.Fiatfon is secreted into breast milk. Nursing mother should be made whether to discontinue nursing or discontinue the drug during taking this drug.
**Dosage and directions for use:**
*Acute gastric ulcer and 12 duodenal ulcer* – 40 mg once a day at bedtime or 20 mg two times a day. If necessary, the daily dose can be increased to 80-160 mg. Duration of treatment - 4-8 weeks.
*Prevention of relapse of peptic ulcer*- 20 mg once a day at bedtime.
*Zollinger-Ellison syndrome* - an initial dose of 20 - 40 mg 4 times a day, if necessary, the daily dose can be increased to 240-480 mg. Treatment continued so long as is necessary (severe symptoms - up to 160 mg every 6 hours).
*Reflux esophagitis* initial dose - 20 mg 2 times a day for up to6 weeks (if needed - 20-40 mg 2 times a day for up to 12 weeks).
*Prevent aspiration of gastric contents* - 40 mg before surgery or in the morning of surgery.
*Patients with a creatinine clearance of less than 10 ml/min* - 20 mg at bedtime.
Interval between doses may be increased to 36-48 hours.
**Side-effects:**
*Gastrointestinal:* loss of appetite, dry mouth, nausea, vomiting, abdominal pain, liver enzyme abnormalities, constipation, diarrhea, jaundice, hepatocellular, cholestatic or mixed hepatitis, acute pancreatitis.
*Nervous system disorders:* headache, fatigue, insomnia, fatigue, drowsiness, anxiety, depression, anxiety, psychosis, dizziness, confusion, hallucinations, hyperthermia.
*Cardiovascular:* hypotension, bradycardia, AV block, arrhythmia, vasculitis.
*Allergic reactions:* urticaria, rash, pruritus, bronchospasm, angioneurotic edema,exfoliative dermatitis, Stevens-Johnson syndrome, toxic epidermal necrolysis, anaphylaxis.
*Hematologic:* neutropenia, leukopenia, thrombocytopenia, hemolytic anemia, agranulocytosis, pancytopenia.
*Special Senses:* tinnitus, taste disorder.
*Urogenital:* long-term large doses - decreased potency and libido.
Musculoskeletal: arthralgia, myalgia.
*Other:* bronchospasm, dry skin, alopecia, gynecomastia.
**Overdose:**
*Symptoms:* vomiting, motor agitation, tremor, tachycardia, hypotension, collapse.
*Treatment:* In acute famotidine overdose, usual measure to remove unabsorbed drug from GI tract and clinical monitoring should be employed as soon as possible. Supportive and symptomatic treatment should be initiated.
**Drug interaction:**
In an application with antacids containing magnesium or aluminum, sucralfate may decrease the intensity absorption of famotidine, so the interval between administrations of these drugs should be at least 1-2 hours.
Famotidine, may decrease the absorption of itraconazole and ketoconazole.
Drugs to bone marrow suppression increase the risk of neutropenia.
Depresses the hepatic metabolism of diazepam, geksobarbital, propranolol, lidocaine, phenytoin, theophylline, indirect anticoagulants.
**Cautions:**
Symptoms of peptic ulcer 12 - duodenal ulcer may disappear within 1-2 weeks, treatment should be continued for as long as the scarring is not confirmed by x-ray or endoscopy. Fiatfon may mask symptoms associated with carcinoma of the stomach, so prior to treatment is necessary to exclude the presence of malignant neoplasms. Gradually withdraw because of risk of syndrome "ricochet" in abrupt cancellation.
Long-term treatment in immunocompromised patients, as well as in stress may bacterial lesions of stomach with subsequent spread of infection.
During treatment should avoid eating food, drinks and other drugs that can cause irritation of the mucous membrane of the stomach. *Smoking reduces* the efficacy in inhibiting nocturnal gastric acid secretion.
Burn patients may need to increase the dose due to increased clearance.
In case of missed dose, it should be taken as soon as possible, soon as you remember unless it is nearly time for your next *dose*, in which *case* leave out the *missed dose*. In the absence of improvements, necessary call to doctor.
**Presentation:**
*Fiatfon 20 mg:* 2x14, PVC white opeque blister in a monocarton with instruction for use.
*Fiatfon 40 mg:* 1x14, PVC white opeque blister in a monocarton with instruction for use.
**Storage:**
Keep in dry place, protected from light at a temperature below 30°C. Keep out of reach of children.
**Shelf life:**
Labeled. Do not use after expiry date.
**Distribution Condition:**
Prescribed medicine.