

Famotidine Cas No. : 76824-35-6

Famotidine is used to treat ulcers of the stomach or intestines. It may be used to prevent intestinal ulcers from returning after treatment. This medication is also used to treat certain stomach and throat problems caused by too much acid (e.g., Zollinger-Ellison syndrome, erosive esophagitis) or a backward flow of stomach acid into the esophagus (gastroesophageal reflux disease-GERD).

Active Pharmaceuticals Ingredients Manufacturers



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Taj Pharmaceuticals Ltd.**Famotidine****CAS No. : 76824-35-6**

Systematic (IUPAC) name

3-([2-(diaminomethyleneamino)thiazol-4-yl]methylthio)-N'-sulfamoylpropanimidamide

Identifiers

CAS number 76824-35-6

ATC code A02BA03

PubChem 3325

DrugBank APRD00296

ChemSpider 3208

Chemical dataFormula C₈H₁₅N₇O₂S₃

Mol. mass 337.449 g/mol

Pharmacokinetic data

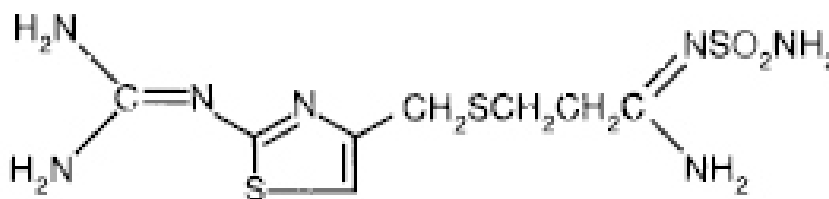
Bioavailability 20–66%

Protein binding 10–28%

Metabolism hepatic-less than 30%

Half life 2.5–4 hours (clinical half-life 8–12 hours)

Excretion Principally excreted unchanged in urine

**USES**

Famotidine is used to treat ulcers of the stomach or intestines. It may be used to prevent intestinal ulcers from returning after treatment. This medication is also used to treat certain stomach and throat problems caused by too much acid (e.g., Zollinger-Ellison syndrome, erosive esophagitis) or a backward flow of stomach acid into the esophagus (gastroesophageal reflux disease-GERD).

Famotidine is known as an H₂ histamine blocker. It works by reducing the amount of acid in your stomach. This helps heal and prevent ulcers and improves symptoms such as heartburn and stomach pain.

HOW TO USE

Take this medication by mouth with or without food, usually once or twice daily or as directed by your doctor. If you are taking this medication once daily, it is usually taken at bedtime.

The dosage and length of treatment are based on your medical condition and response to therapy. In children, dosage may also be based on body weight. You may take other medications (e.g., antacids) for your condition as recommended by your doctor. Follow your doctor's instructions carefully. Consult your doctor or pharmacist if you have any questions.

Take this medication regularly in order to get the most benefit from it. To help you remember, take it at the same time(s) each day. Do not increase your dose or take it more often than prescribed. Do not stop taking this medication without your doctor's approval because this may delay healing of the ulcer.

If you are using nonprescription famotidine for self-treatment of acid indigestion or heartburn, take 1 tablet by mouth with a glass of water as needed. To prevent heartburn, take 1 tablet by mouth with a glass of water 15-60 minutes before eating food or drinking beverages that cause heartburn.



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Do not use more than 2 tablets in 24 hours unless directed by your doctor. Do not take for more than 14 days in a row without talking with your doctor.

SIDE EFFECTS

Headache, constipation, diarrhea, or dizziness may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly.

If your doctor has directed you to use this medication, remember that he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

Tell your doctor immediately if any of these rare but very serious side effects occur: easy bruising/bleeding, fast/slow/irregular heartbeat, signs of infection (e.g., fever, persistent sore throat, cough), mental/mood changes (e.g., restlessness, confusion, depression, hallucinations), persistent nausea/vomiting, seizure, severe stomach/abdominal pain, dark urine, yellowing skin/eyes.

A very serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction may include: rash, itching, swelling, severe dizziness, trouble breathing.

PRECAUTIONS

Before taking famotidine, tell your doctor or pharmacist if you are allergic to it; or to other H2 blockers such as cimetidine, ranitidine; or if you have any other allergies.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: immune system problems, kidney problems, liver problems, lung problems (e.g., asthma, chronic obstructive pulmonary disease-COPD), other stomach problems (e.g., tumors).

Some symptoms may actually be signs of a more serious condition. Tell your doctor immediately if you have: heartburn combined with lightheadedness/sweating/dizziness, chest pain or shoulder/jaw pain (especially with trouble breathing), pain spreading to arms/neck/shoulders, unexplained weight loss.

This drug may make you dizzy; use caution while engaging in activities requiring alertness such as driving or using machinery. Limit alcoholic beverages.

Do not use to treat children younger than 12 unless directed by the doctor.

Kidney function declines as you grow older. This medication is removed by the kidneys. Therefore, elderly people may be at greater risk for side effects while using this drug. Caution is advised when using this drug in the elderly because they may be more sensitive to its effects, especially confusion and dizziness.

Famotidine should be used only when clearly needed during pregnancy. Discuss the risks and benefits with your doctor.

MISSED DOSE

If you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE

Store at room temperature at 77 degrees F (25 degrees C) away from light and moisture. Brief storage between 59-86 degrees F (15-30 degrees C) is permitted.



Store the nonprescription medication at room temperature between 68-86 degrees F (20-30 degrees C). Do not store in the bathroom. Keep all medicines away from children and pets.

DOSAGE

Use famotidine exactly as directed on the label, or as prescribed by your doctor. Do not use it in larger amounts or for longer than recommended. Follow your doctor's instructions.

The chewable tablet must be chewed thoroughly before swallowing. Shake the oral suspension (liquid) for 5 to 10 seconds before you measure a dose. To be sure you get the correct dose, measure the liquid with a marked measuring spoon or medicine cup, not with a regular table spoon. If you do not have a dose-measuring device, ask your pharmacist for one. Although most ulcers heal within 4 weeks of famotidine treatment, it may take up to 8 weeks of using this medicine before your ulcer heals. For best results, keep using the medication as directed. Talk with your doctor if your symptoms do not improve after 6 weeks of treatment.

Famotidine may be only part of a complete program of treatment that also includes changes in diet or lifestyle habits. Follow your doctor's instructions very closely. Store famotidine at room temperature away from moisture, heat, and light. Throw away any unused famotidine liquid that is older than 30 days.

DRUG DESCRIPTION

The active ingredient famotidine is a histamine H₂-receptor antagonist. Famotidine is N'-(aminosulfonyl)-3,2-(diaminomethylene)amino]-4-thiazolyl]methyl]thio]propanimidamide. The empirical formula of famotidine is C₈H₁₅N₇O₂S₃ and its molecular weight is 337.43.

Famotidine is a white to pale yellow crystalline compound that is freely soluble in glacial acetic acid, slightly soluble in methanol, very slightly soluble in water, and practically insoluble in ethanol.

Each tablet for oral administration contains either 20 mg or 40 mg of famotidine and the following inactive ingredients: hydroxypropyl cellulose, hydroxypropyl methylcellulose, iron oxides, magnesium stearate, microcrystalline cellulose, corn starch, talc, and titanium dioxide.

Each Orally Disintegrating Tablet for oral administration contains either 20 mg or 40 mg of famotidine and the following inactive ingredients: aspartame, mint flavor, gelatin, mannitol, red ferric oxide, and xanthan gum.

Note /Government Notification: These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to the manufacture of the substances. For any (Control Substance) products Import and Export *** subjected to your country government laws /control substance ACT.

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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:

<http://www.tajapi.com>

or by contacting the sponsor, Taj Pharmaceuticals Limited., at:

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