

Safety Data Sheet

Product Name: Ibuprofen and famotidine tablets

Strength: 800 mg / 26.6 mg

Pack Size: HDPE Bottle pack of 90's

Revision No.: 00

EMERGENCY OVERVIEW

Each Tablets intended for oral administration contains Ibuprofen, Famotidine and excipients generally considered to be non- toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

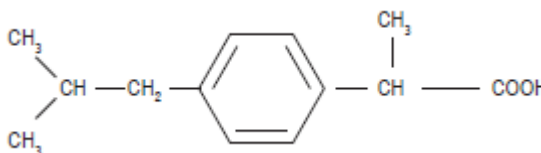
Section 1. Identification

Identification of the product

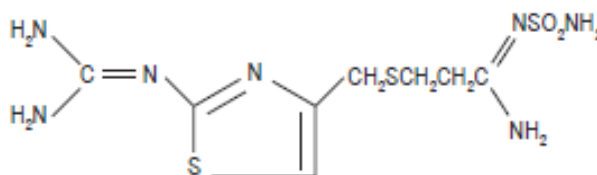
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Chemical Name: Ibuprofen, USP is (\pm)-2-(*p*-isobutylphenyl) propionic acid. Its molecular formula is $C_{13}H_{18}O_2$ and molecular weight is 206.28.

Its Structural formula is:



Famotidine, USP is *N'*-(aminosulfonyl)-3-[[[2-[(diaminomethylene)amino]-4-thiazolyl]methyl]thio]propanimidamide. Its molecular formula is $C_8H_{15}N_7O_2S_3$ and molecular weight is 337.45.



Manufacturer / supplier identification

Company: Zyclus Lifesciences Ltd., Matoda, India

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Recommended use / Therapeutic Category

Ibuprofen and famotidine tablets, a combination of the NSAID ibuprofen and the histamine H₂-receptor antagonist famotidine, is indicated for the relief of signs and symptoms of rheumatoid arthritis and osteoarthritis and to decrease the risk of developing upper gastrointestinal ulcers, which in the clinical trials was defined as a gastric and/or duodenal ulcer, in patients who are taking ibuprofen for those indications.

Restriction on Use / Contraindications:

Ibuprofen and famotidine tablets are contraindicated in the following patients:

- Known hypersensitivity (e.g., anaphylactic reactions and serious skin reactions) to ibuprofen or famotidine or any components of the drug product.
- History of asthma, urticaria or other allergic-type reactions after taking aspirin or other NSAIDs. Severe, sometimes fatal, anaphylactic reactions to NSAIDs have been reported in such patients.
- In the setting of coronary artery bypass graft (CABG) surgery.
- Ibuprofen and famotidine tablets should not be administered to patients with a history of hypersensitivity to other H₂-receptor antagonists. Cross sensitivity with other H₂-receptor antagonists has been observed.

Section 2. Hazard(s) Identification

Dosage and Administration

- The recommended daily dose of ibuprofen and famotidine 800 mg/26.6 mg is a single tablet administered orally three times per day.
- Ibuprofen and famotidine tablets should be swallowed whole and should not be cut to supply a lower dose. Do not chew, divide or crush tablets.
- Patients should be instructed that if a dose is missed, it should be taken as soon possible. However, if the next scheduled dose is due, the patient should not take the missed dose and should be instructed

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	to take the next dose on time. Patients should be instructed not to take 2 doses at one time to make up for a missed dose.
Adverse Effects	<ul style="list-style-type: none">• Do not substitute ibuprofen and famotidine tablets with the single-ingredient products of ibuprofen and famotidine.• Most common adverse reactions ($\geq 1\%$ and greater than ibuprofen alone) are nausea, diarrhea, constipation, upper abdominal pain and headache.• The following serious adverse reactions are :<ul style="list-style-type: none">▪ Cardiovascular Thrombotic Events▪ GI Bleeding, Ulceration and Perforation▪ Hepatotoxicity▪ Hypertension▪ Heart Failure and Edema▪ Renal Toxicity and Hyperkalemia▪ Anaphylactic Reactions▪ Seizures▪ Serious Skin Reactions▪ Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)▪ Fetal Toxicity▪ Hematologic Toxicity▪ Aseptic Meningitis▪ Ophthalmological Effects
Overdosage	Symptoms following acute NSAID overdosages have been typically limited to lethargy, drowsiness, nausea, vomiting and epigastric pain, which have been generally reversible with supportive care. Gastrointestinal bleeding has occurred. Hypertension, acute renal failure, respiratory depression and coma have occurred but were rare.

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Pregnancy Comments Use of NSAIDs, including ibuprofen and famotidine tablets, can cause premature closure of the fetal ductus arteriosus and fetal renal dysfunction leading to oligohydramnios and, in some cases, neonatal renal impairment. Because of these risks, limit dose and duration of ibuprofen and famotidine tablets use between about 20 weeks and 30 weeks of gestation and avoid ibuprofen and famotidine tablets use at about 30 weeks of gestation and later in pregnancy.

Pregnancy Category Not Assigned

Section 3. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component:		
Ibuprofen	0.5 mg/ day	15687-27-1
Famotidine	1.33 mg/ day	76824-35-6
Inactive ingredients:		
Microcrystalline Cellulose	Not Found	9004-34-6
Hypromellose	Not Found	9004-65-3
Croscarmellose Sodium	Not Found	74811-65-7
Hydroxypropyl Cellulose	Not Found	9004-64-2
Colloidal Silicon Dioxide	Not Found	7631-86-9
Magnesium Stearate	Not Found	557-04-0
Opadry AMB II White	Not Found	117698-04-1
Opadry Clear	Not Found	117698-04-1
Opacode Black	Not Found	1309-33-3
Isopropyl Alcohol	Not Found	67-63-0

Section 4. First -aid measures

In Case of Inhalation

- Allow the victim to rest in a well-ventilated area. Seek immediate medical attention.

In Case of Skin Contact

- After contact with skin, wash immediately with plenty of water. Gently and thoroughly wash the contaminated skin with running water and non-abrasive soap. Be particularly careful to clean folds, crevices, creases and groin. Cover the irritated skin with an

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| In Case of Eye Contact | <ul style="list-style-type: none">• emollient. If irritation persists, seek medical attention. Wash contaminated clothing before reusing. |
| In Case of Ingestion | <ul style="list-style-type: none">• Check for and remove any contact lenses. Do not use an eye ointment. Seek medical attention.• Do not induce vomiting. Examine the lips and mouth to ascertain whether the tissues are damaged, a possible indication that the toxic material was ingested; the absence of such signs, however, is not conclusive. Loosen tight clothing such as a collar, tie, belt or waistband. If the victim is not breathing, perform mouth-to-mouth resuscitation. Seek immediate medical attention. |

Section 5. Fire -fighting measures

Flammability of the Product: May be combustible at high temperature.

Products of Combustion These products are carbon oxides (CO, CO₂).

Explosion Hazards in Presence of Various Substances: Risks of explosion of the product in presence of mechanical impact: Not available. Risks of explosion of the product in presence of static discharge: Not available.

Fire Fighting Media and Instructions: SMALL FIRE: Use DRY chemical powder. LARGE FIRE: Use water spray, fog or foam. Do not use water jet.

Section 6. Accidental release measure

Spill Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

Section 7. Handling and Storage

Precaution for safe handling Keep away from heat. Keep away from sources of ignition. Empty containers pose a fire risk,

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Ground all equipment containing material. Do not ingest. Do not breathe dust. Wear suitable protective clothing In case of insufficient ventilation, wear suitable respiratory equipment If ingested, seek medical advice immediately and show the container or the label. Avoid contact with skin and eyes.

Conditions for safe storage Keep container dry. Keep in a cool place. Ground all equipment containing material. Keep container tightly closed. Keep in a cool, well-ventilated place. Combustible materials should be stored away from extreme heat and away from strong oxidizing agents.

Section 8. Exposure control / Personal Protection

Exposure Limit No data available

Hygiene measures Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of the product handle.

Section 9. Physical and chemical properties

Physical States / Description	Ibuprofen and famotidine tablets 800 mg / 26.6 mg are white to off-white colored, modified capsule shaped, film-coated beveled edge tablets imprinted with "777" on one side and plain on other side		
Solubility / Miscibility in water	Soluble in water	Decomposition	No Data
Molecular weight	Ibuprofen: 206.28. Famotidine: 337.45	Temperature:	
Evaporation rate	No Data	Melting Point	75°C (167°F)
Reactivity in water	No Data	Vapour density	No Data
% Volatile by volume	No Data	Vapour pressure	No Data
		Specific gravity	No Data

Section 10. Stability and Reactivity

Chemical Stability The Product is stable.

Conditions to avoid: Not Applicable

Materials to avoid: Not Applicable

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Incompatibility with various substances Not Applicable

Section 11. Toxicological information

Chronic Effect on Humans Substance is toxic to blood, lungs, the nervous system, mucous membranes.

Toxic Effect on Humans Very hazardous in case of ingestion, of inhalation. Hazardous in case of skin contact (irritant). Slightly hazardous in case of skin contact (permeator).

Section 12. Ecological information

Ecotoxicity No data available

Other adverse effects No data available

Section 13. Disposal Consideration

Dispose in accordance with local, state, and federal regulations

Section 14. Transport Information

The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG). In accordance with ADR / RID / IMDG / IATA / AND.

Section 15. Regulatory Information

ANDA no. is 218684.

Section 16. Other information

None

Date of issue: 14/05/25

Supersedes edition: New Edition

The information contained herein is based on the state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.