

SAFETY DATA SHEET

According to Globally Harmonized System of Classification and Labelling of Chemicals (GHS),
Tenth Revised Edition UNITED NATIONS
New York and Geneva, 2023

FAMOTIDINE TABLETS USP 20MG & 40MG

1. IDENTIFICATION

GHS Product identifier: FAMOTIDINE TABLETS USP 20MG & 40MG

Product code: #

Chemical Description: 3-[[2-(diaminomethylideneamino)-1,3-thiazol-4-yl]methylsulfanyl]-N'-sulfamoylpropanimidamide

Other means of identification:

Recommended use of the chemical: Used to treat stomach ulcers (gastric and duodenal), erosive esophagitis (heartburn or acid indigestion), and gastroesophageal reflux disease (GERD).

Restrictions on use: The product should be used only for the above-mentioned use and may not be used for any other purpose than stated above.

Manufactured by:

Mankind Pharma Ltd.,
Unit III, Opp. Dental College, Rampur Ghat,
Teh. -Paonta Sahib (HP-173025), India.
CIN No.: L74899DL1991PLC044843

Emergency phone number: +91 1704227600

2. HAZARDS IDENTIFICATION

Classification

Globally Harmonized System, UN (GHS)

Classification	Category	Exposure Route
Skin irritation	2	Dermal
Eye irritation	2	

Labeling

Globally Harmonized System, UN (GHS)



Classification	
Signal Word	Warning
Hazard Statements:	H302+H332 Harmful if swallowed or if inhaled H317: May cause an allergic skin reaction H315: Causes skin irritation H319: Causes serious eye irritation
Precautionary Statements:	P261: Avoid breathing dust. P264: Wash hands thoroughly after handling. P273: Avoid release to the environment. P280: Wear protective gloves/protective clothing/eye protection/face protection. P305 + P351 + P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P332+P313 If skin irritation occurs: Get medical advice/attention. P337+P313: If eye irritation persists: Get medical advice/attention. P311: Call a poison centre/physician P391: Collect spillage
Other hazards	Control formation and generating of dusts during use.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical nature: Mixture containing Midodrine HCl

Hazardous ingredients	CAS	Content
Famotidine	76824-35-6	9.7 - 10mg 19.4 - 40mg
Microcrystalline cellulose	9004-34-6	-
Hydroxypropyl Methylcellulose	9004-65-3	-
Lactose Monohydrate	64044-51-5	-
Crosscarmellose Sodium	74811-65-7	-
Colloidal Silicon dioxide	112945-52-5, 7631-86-9	-
Magnesium Stearate (Ligamed MF-2-V)	557-04-0	< 2%

4. FIRST-AID MEASURES

Inhalation

Move the person into fresh air. In case of respiratory symptoms, place the person in a semi-seated position and administer oxygen. If not breathing, give artificial respiration. Consult a physician.

Skin contact

Wash off with soap and plenty of water. Take victim immediately to hospital. Consult a physician.

Eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Ingestion

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

5. FIRE-FIGHTING MEASURES

Fire extinguishing agents

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Fire/explosion hazard

Fine particles (such as dust and mists) may fuel fires/explosions.

Hazardous combustion products

Formation of toxic gases is possible during heating or fire.

Personal protection

Self-contained breathing apparatus. Fire-fighters must wear self-contained breathing apparatus for firefighting if necessary.

Special exposure hazards

Do not release chemically contaminated water into drains, soil or surface water. Dispose of contaminated water and soil according to local regulations.

6. ACCIDENTAL RELEASE MEASURES

Personal protection

Goggles, gloves, protective clothing, respiratory protection.
Remove ignition sources and provide sufficient ventilation.

Environmental precautions

Prevent contamination of soil, drains and surface waters.

Spillage procedure

Take up mechanically and collect in suitable container (adequately labelled) for disposal.

7. HANDLING AND STORAGE

Handling

Minimize dust generation and accumulation. If tablets are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Occupational hygiene

Avoid ingestion, inhalation, skin and eye contact. Handle in accordance with good industrial hygiene practice and any legal requirements.

Conditions for safe storage

Avoid dust formation and ignition sources. Ensure good local exhaust ventilation.
Keep away from heat/sparks/open flames/hot surfaces – No smoking.

Storage facilities

Store in a cool, dry area with adequate ventilation. Keep tightly closed.

Segregation

Store locked up.

Storage conditions

Keep containers closed.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Exposure limit values

Components with occupational exposure limits

CAS No	Name	OEL
9004-34-6	Microcrystalline cellulose	ACGIH TLV TWA 10 mg/m ³
112945-52-5, 7631-86-9	Colloidal silicon dioxide	Australia TWA 2 mg/m ³
557-04-0	Magnesium Stearate	TWA 10 mg/m ³

Occupational exposure controls

Appropriate engineering controls

Maintain air concentrations below occupational exposure standards. Prevent dust formation.

General Personal Protection

Goggles, gloves, protective clothing.

Respiratory protection

Not required for the normal use of this product. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

Hand protection

Protective gloves.

Eye protection

Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin and body protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance & Colour: 20mg - Beige colored tablets & 40mg Tan colored tablets.

Form: Tablets

Odour: Not specific

pH: Not available

Melting point: Data not available

Boiling point: Not applicable

Flash point: Not applicable

Auto-ignition temperature: Data not available

Decomposition temperature: Data not available

Density: Not available

Solubility in solvents: Data not available

10. STABILITY AND REACTIVITY

Conditions to avoid

No decomposition under normal conditions

Materials to avoid

None

Hazardous decomposition products

carbon dioxide, carbon monoxide, nitrogen oxides, sulfur oxides

11. TOXICOLOGICAL INFORMATION

Acute toxicity

Famotidine 100% active ingredient has been tested for acute toxicity and belongs to category 4.

Famotidine

Rat Oral LD₅₀ 4049 mg/kg

Rat IV LD₅₀ 254 mg/kg

Microcrystalline cellulose

Rat Oral LD₅₀ > 5000 mg/kg

Rabbit Dermal LD₅₀ > 2000 mg/kg

Magnesium stearate

Rat Oral LD₅₀ > 2000 mg/kg

Rat Inhalation LC₅₀ > 2000 mg/m³

Lactose monohydrate

Rat Oral LD₅₀ 29700 mg/kg

Based on the toxicity data, Famotidine tablets are not classified for acute toxicity.

Primary Irritation

Skin irritation

Magnesium stearate - category 2

Famotidine – category 2

Based on the data, mixture falls in category 2 for skin.

Eye irritation

Magnesium stearate - category 2

Famotidine – category 2A

Based on the 'Decision logic 3.3.2 for serious eye damage/irritation' of GHS classification, mixture is classified as category 2.

Respiratory or Skin sensitization

Mixture is not classified for respiratory or skin sensitization.

CMR consideration:

Germ cell mutagenicity:

Data not available for classification.

GHS Classification is not possible.

Carcinogenicity

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Reproductive toxicity

Reproductive & fertility Rat oral 2000 mg/kg/day NOAEL Fertility

Embryo/fetal development Rat oral 2000 mg/kg/day NOAEL Not teratogenic

Specific target organ toxicity single exposure: (STOT SE)

Famotidine – category 3

Mixture is not classified for organ toxicity on single exposure

Specific target organ toxicity repeated exposure:

Data not available

Aspiration hazard:

Data is not available

Additional information: None

12. ECOLOGICAL INFORMATION

Ecotoxicity

Acute/chronic aquatic toxicity data

- Magnesium stearate - Classified as chronic 4.

Mixture is not classified for ecotoxicity.

Persistence and degradability

Data not available

Bioaccumulation

Data not available

Mobility in soil

Data not available

Behaviour in treatment plants

Data not available.

Additional information

This formulation has not been tested as a whole. Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Product disposal

Observe all local and national regulations when disposing of this material. Disposal must be done through authorised waste disposal firms in compliance with local regulations. Waste should not be released to sewers.

Contaminated packaging

Contaminated, empty containers must be disposed of as chemical waste.

14. TRANSPORT INFORMATION

This substance is not classified as dangerous for transport.
Not regulated for transport of dangerous goods: DOT, IATA, IMDG

15. REGULATORY INFORMATION

CLASSIFICATION AND LABELLING

Compliance with following regulations:

- Globally Harmonized System of Classification and Labelling of Chemicals (GHS), UNECE 2023 as amended.
- UN Recommendations on the Transport of Dangerous Goods, UNECE 2019
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16. OTHER INFORMATION

Recommended restrictions on use

This product should be stored, handled and used in accordance with good industrial hygiene practices and in conformity with any legal regulation. The information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements. It should not therefore be construed as guaranteeing specific properties.

MSDS Changes

Prepared on 12/01/24