SAFETY DATA SHEET

Famotidine for Oral Suspension USP, 40 mg/5mL
Version: 01 **Issue Date: 06/20/2023**

1. IDENTIFICATION:

Product Name: Famotidine for Oral Suspension USP, 40 mg/5mL

Recommended Use: Rx. Pharmaceutical. Use only as directed.

Used Advised Against: Not Available

Distributor: Biocon Pharma Inc.,
485, US Highway 1 S, Ste B-305,
Iselin, New Jersey, 08830-3009
USA
Emergency: (732) 636-2950 or call 911
Information: (732) 636-2950

Manufacturer: Carnegie Pharmaceuticals, LLC
600, Delran pkwy, Unit C,
Delran, New Jersey, 08075
USA
Emergency: (732) 783-7011 or call 911
Information: (732) 783-7011

2. HAZARDS IDENTIFICATION:

Hazard Classification:
Not Classified
This product is a mixture that has not been fully tested as a whole. This product is not considered a hazardous substance.
Label Element:
Not Classified
Other Hazards(s):
No information available
Unknown acute toxicity:
No information available
Health Hazard:
Not classified.
Environment:
No information is available about the potential of this product to produce adverse environmental effects.
Precautionary Statements:
Wash hands thoroughly after handling.
Use of PPE as required. If exposed, get medical attention.

3. COMPOSITION / INFORMATION ON INGREDIENT:

Active Ingredient:	CAS Number:	Strength:
Famotidine	76824-35-6	40 mg/5mL

In-active ingredients are not hazardous

4. FIRST AID MEASURES:

This is a pharmaceutical product in its final form. The following guidance may be used as needed.

General: Consult a physician. Show this safety data sheet to the doctor in attendance.

Medical treatment: Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center. Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc.

Overdosage: The types of adverse reactions in overdosage of famotidine are similar to the adverse reactions encountered with use of recommended dosages. In the event of overdosage, treatment should be symptomatic and supportive. Unabsorbed material should be removed from the gastrointestinal tract, the patient should be monitored, and supportive therapy should be employed. Due to low binding to plasma proteins, famotidine is eliminated by hemodialysis. There is limited experience on the usefulness of hemodialysis as a treatment for famotidine overdosage.

Ingestion: If conscious, give water to drink and induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash mouth with water. Obtain medical attention.

Inhalation: Move individual to fresh air. Obtain medical attention if difficulty in breathing occurs. If not breathing, provide artificial respiratory assistance.

Skin Contact: Remove contaminated clothing and flush exposed areas with large amounts of water. Wash all exposed areas of skin with plenty of soap and water. Obtain medical attention if skin reaction occurs.

Eye contact: Flush eyes with plenty of water. Get medical attention.

5. FIRE FIGHTING MEASURES:

Fire and Explosion Hazards: Assume that this product is capable of sustaining combustion.
Extinguishing media: Water. Carbon dioxide (CO_2). Dry chemical powder.
Special protective actions for fire-fighters: As in any fire, wear self-contained breathing apparatus pressure-demand and full protective gear to prevent contact with skin and eyes.

6. ACCIDENTAL RELEASE MEASURES:

Personal Precautions: Wear suitable protective clothing, gloves, and eye/face protection.
Environmental Precautions: For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
Clean-up methods: Collect and place it in a suitable, properly labeled container for recovery or disposal.

7. HANDLING AND STORAGE:

Handling: No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.
Storage: Store famotidine for oral suspension dry powder and constituted suspension at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
Protect from freezing. Discard unused constituted suspension after 30 days.

Dispense in a USP tight, light-resistant container.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION:

Exposure Limits: Not established.
Personal Protection Recommendations:
Ventilation: A local and/or general exhaust system is recommended to minimize airborne contaminants.
Respirator: Use a powered or air-purifying respirator meeting an approved standard if indicated by environmental assessment. Selection should be based upon anticipated exposure and capacity of respirator.
Gloves: Impervious gloves should be worn.
Clothing: Wear clean, body-covering protective clothing that is suitable for the task being performed.
Eye protection: Utilize safety eyewear that complies with an approved standard when protection from splash, mist or dust is required.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Product Strength: Famotidine for Oral Suspension, USP 40mg/5mL
Physical State: Solid
Color: White to off-white
Shape: N/A
Deboss/Imprint: N/A
Odor: Cherry Banan Peppermint
pH: No data available
Boiling point: No data available
Odor threshold: No data available
pH: No data available
Melting point/melting range: No data available
Boiling point/boiling range: No data available
Flash point: No data available
Evaporation rate: No data available
Flammability: No data available
Upper/lower flammability or explosive limits: No data available
Auto ignition temperature: No data available
Danger of explosion: No data available
Vapor pressure: No data available
Vapor density: No data available
Relative density: No data available
Solubility in/Miscibility with water: No data available

10. STABILITY AND REACTIVITY:

Stable under recommended storage conditions.

11 TOXICOLOGICAL INFORMATION:

Not fully established. This product is a mixture that has not been fully tested as a whole. Information provided herein is derived from the approved product insert and/or supplier SDS for active ingredients.

Toxicity Data: Oral LD50 for Famotidine USP = 4049 mg/kg (Rat)
Carcinogenicity: There was no evidence of carcinogenic potential for Famotidine.
Reproductive Effects: Studies in rats and rabbits with oral doses of up to 2,000 and 500 mg/kg of body weight per day respectively, have not shown that famotidine impairs fertility.

12 ECOLOGICAL INFORMATION:

No information available

13 DISPOSAL CONSIDERATIONS:

Incinerate in an approved facility. Follow all federal state and local environmental regulations.

14 TRANSPORT INFORMATION:

Refer to the bill of lading for proper shipping information.
Special considerations: N/A

15 REGULATORY INFORMATION:

Individual containers are labeled in accordance with U.S. FDA regulations for finished pharmaceuticalproducts.
Drug Status: Rx Only
Schedule: Non-controlled

16 OTHER INFORMATION:

Not applicable

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