

SAFETY DATA SHEET (SDS)

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Famotidine for Oral Suspension, 40mg/ 5mL

Effective date: 07/22/2025

1. Product Information

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

2. Composition

Ingredients: Famotidine

3. Hazards Identification

Fire and Explosion : Expected to be non-combustible.

Health Hazards : No information is available

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

4. First Aid Measures

Description of First Aid Measures

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

Eye Contact: Immediately flush eyes with water. If irritation occurs or persist, get medical attention.

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.

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-unconscious. Wash mouth with water. Obtain medical attention.

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

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 od adverse reactions in over dose of famotidine are similar to the adverse reactions encountered with use of recommended dosages. In the event of over dosage,



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treatment should be symptomatic and Supportive. Unabosrbed 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.

5. Fire Fighting Measures

Fire and Explosion Hazards: Assume that this product is capable of sustaining combustion.

Extinguishing Media:

Extinguish fires with CO2, 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, sewer, or surface drainage systems.

Methods and Material for Containment and Cleaning Up

Clean up methods: Collect and place it in a suitable, properly labeled container for recovery or disposal.

7. Handling and Storage

Precautions for Safe 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.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store the Famotidine for oral suspension dry powder and constituted suspension at 25°C (77°F); excursions permitted between 15°C and 30°C (59°F and 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.



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8. Exposure Controls/Personal Protection

Exposure Limits: Not established

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

Physical State: Solid

Odor: Cherry Banana Peppermint

Color: White to off-white

10. Stability and Reactivity

Stable under recommended storage conditions.

11. Toxicological Information

Information on Toxicological Effects

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



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13. Disposal Considerations

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

14. Transport Information

International Regulations: Not Classified by transport regulations, non-regulated

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 pharmaceutical products.

Drug Status: Rx Only **Schedule:** Non-controlled

16. Other Information

Prepared by: MSN Pharmaceutical Inc, Piscataway, New Jersey – 08554

MSN Pharmaceutical Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

Disclaimer: This SDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. It is not meant to be an all-inclusive document on worldwide hazard communications regulations. This information is offered in good faith. Each user of this material needs to evaluate the conditions of use and design the appropriate mechanisms to prevent employee exposures, property damage or release to the environment.

End of Safety Data Sheet