Annora

SAFETY DATA SHEET

Section 1: Identification	
Material	Famotidine for Oral Suspension USP 40 mg/5 mL
Manufacturer	Annora Pharma Ltd.
Section 2: Hazard(s) Identification	
Fire and Explosion	Expected to be non-combustible.
Health	Famotidine for oral suspension is contraindicated in patients with a history of serious hypersensitivity reactions (e.g., anaphylaxis) to famotidine or other histamine-2 (H2) receptor antagonists.
Environment	No information is available about the potential of this product to produce adverse environmental effects.
Section 3: Composition/Information on Ingredients	
Ingredient	**CAS#**
Famotidine	76824-35-6
Banana Flavour	NA
Cherry-flavour	NA
Citric acid	77-92-9
Isopropyl alcohol	67-63-0
Methylparaben sodium	5026-62-0
Peppermint-flavor	NA
Powdered Cellulose	9004-34-6
Propylparaben sodium	35285-69-9
Sodium Benzoate	532-32-1
Sucrose	57-50-1
Xanthan gum	11138-66-2
Section 4: First-Aid Measures	
Eye Contact	Flush eyes with plenty of water. Get medical attention.
Skin Contact	Remove contaminated clothing and flush exposed area with large amounts of water. Wash all exposed areas of skin with plenty of soap and water. Obtain medical attention if skin reaction occurs.
Inhalation	Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance.
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 out the mouth with water.

Notes to Health Professionals 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.
Section 5: Fire-Fighting Measures	
Fire-fighting measures Fire and Explosion Hazards	Assume that this product is capable of sustaining combustion
Extinguishing Media	Water. Carbon dioxide (CO2). Dry chemical powder
Special Firefighting Procedures	Wear self-contained breathing apparatus and protective clothing
Hazardous Combustion Products	Hazardous combustion or decomposition products are expected when the product is exposed to fire.
Section 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
Section 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 controls/personal protection	Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

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Section 9: Physical and Chemical Properties	
Physical State	Powder
Description	White to off-white granular powder. When constituted as directed, famotidine for oral suspension is a white to off-white homogeneous suspension with a cherry-banana-mint flavor, containing 40 mg of famotidine per 5 mL. 40 mg - NDC - 31722-063-31
Section 10: Stability and Reactivity	
Stability and Reactivity	Stable under recommended storage conditions.
Section 11: Toxicological Information	
Information on Toxicological Effects Carcinogenesis, Mutagenesis, Impairment of Fertility	• Carcinogenic potential of famotidine was assessed in a 106-week oral carcinogenicity study in rats and a 92-week oral carcinogenicity study in mice. In the 106-week study in rats and the 92-week study in mice at oral doses of up to 2000 mg/kg/day (approximately 243 and 122 times, respectively, based on body surface area, the recommended human dose of 80 mg per day for the treatment of erosive esophagitis), there was no evidence of carcinogenic potential for famotidine. • Famotidine was negative in the microbial mutagen test (Ames test) using Salmonella typhimurium and Escherichia coli with or without rat liver enzyme activation at concentrations up to 10,000 mcg/plate. • In in vivo studies in mice, with a micronucleus test and a chromosomal aberration test, no evidence of a mutagenic effect was observed. • In studies with rats given oral doses of up to 2000 mg/kg/day (approximately 243 times, based on body surface area, the recommended human dose of 80 mg per day) fertility and reproductive performance were not affected.
Section 12: Ecological Information	
Ecological Information	No relevant studies identified.
Section 13: Disposal Considerations	
Disposal Considerations	Incinerate in an approved facility. Follow all federal state and local environmental regulations.

Section 14: Transport Information

IATA/ICAO - Not Regulated
IATA Proper shipping Name : N/A
IATA UN/ID No : N/A IATA Hazard Class : N/A
IATA Packaging Group : N/A
IATA Label : N/A
IMDG - Not Regulated
IMDG Proper shipping Name : N/A
IMDG UN/ID No : N/A
IMDG Hazard Class : N/A
IMDG Flash Point : N/A
IMDG Label : N/A
DOT - Not Regulated
DOT Proper shipping Name : N/A
DOT UN/ID No : N/A
DOT Hazard Class : N/A
DOT Flash Point : N/A
DOT Packing Group : N/A
DOT Label : N/A

Section 15: Regulatory Information

This Section Contains Information relevant to compliance with other Federal and/or state laws

Section 16: Other Information, including date of preparation or last revision

Issue Date: 29-08-2023

Version: 00

Further information

Revision date: NA

Revision note: NA

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Annora shall not be held liable for any damage resulting from handling or from contact with the above product. Annora reserves the right to revise this SDS.