NOVADOZ
AN MSN COMPANY

FAMOTIDINE FOR ORAL SUSPENSION-- 40 mg/5 mL

S.No.	Category	Question	Answer
Clinical Particulars			
1	Use/Indication	What is the product indicated for?	**Adults:** • Active duodenal ulcer (DU) and gastric ulcer (GU). • Symptomatic nonerosive gastroesophageal reflux disease (GERD). • Erosive esophagitis due to GERD. • Pathological hypersecretory conditions (e.g., Zollinger-Ellison syndrome). • Reduction of the risk of recurrent duodenal ulcer. **Pediatric Patients:** • ≥1 year: Peptic ulcer and GERD (with or without esophagitis and ulceration). • Birth to <1 year: GERD.
2	Dosage	What is the recommended dosage?	Adults • Active duodenal ulcer (DU): 40 mg once daily or 20 mg twice daily. • Active gastric ulcer (GU): 40 mg once daily. • Symptomatic nonerosive GERD: 20 mg twice daily. • Erosive esophagitis due to GERD: 20 mg twice daily or 40 mg twice daily. • Pathological hypersecretory conditions: 20 mg every 6 hours; adjust based on patient response (maximum 160 mg every 6 hours). • Reduction of recurrent DU: 20 mg once daily. Pediatric Patients Peptic Ulcer Disease (1 year to <17 years): • Initial dose: 0.5 mg/kg once daily or 0.25 mg/kg twice daily. • May increase to 1 mg/kg once daily at bedtime or 0.5 mg/kg twice daily.

			• Maximum: 40 mg/day. GERD • Birth to <3 months: 0.5 mg/kg once daily; may increase to 1 mg/kg once daily. • 3 months to <1 year: 0.5 mg/kg twice daily; may increase to 1 mg/kg twice daily (maximum 40 mg/day). GERD with or without esophagitis and ulcerations (1 year to <17 years): • 0.5 mg/kg twice daily (maximum 40 mg twice daily).
3	Administration	How do I take it?	• Shake the bottle well before each use. • Take it once daily at bedtime or twice daily (morning and bedtime), as directed by your healthcare provider. • It can be taken with or without food. • It can be taken with antacids, if needed.
4	Formulation	Can tablet be crushed?	NA
5	Administration	What do I do if I miss a dose?	If you miss a dose of Famotidine Oral Suspension continue your prescribed course of therapy, and contact your physician immediately.
6	Administration	Use in Pediatric Population	Infants (Birth to 12 months): • Oral bioavailability is approximately 42% after a 0.5 mg/kg dose. • Drug exposure (AUC) increases 1.4-fold after a single 1 mg/kg dose and 2.7-fold after multiple 1 mg/kg doses compared with 0.5 mg/kg. • Plasma clearance is lower and elimination half-life is longer in infants, particularly those <3 months of age. Children (11 to 15 years): • Mean oral bioavailability is approximately 50%, comparable to adults (42–49%).

7	Administration	Use in Geriatric Population	• Famotidine is known to be substantially excreted by the kidney, and the risk of adverse reactions to famotidine for oral suspension may be greater in elderly patients, particularly those with impaired renal function. • In general, use the lowest effective dose of famotidine for oral suspension for an elderly patient and monitor renal function
8	Mechanism	Mechanism of Action	Famotidine reduces the amount of acid your stomach makes by blocking signals that tell the stomach to produce acid. This helps relieve heartburn and acid reflux, heal stomach and intestinal ulcers, and protect the stomach from too much acid. It also reduces the amount of digestive enzyme (pepsin) released, along with stomach acid.
9	Warning	Black Box Warning	None
10	Lactation	Use in Lactation	• There are limited data available on the presence of famotidine in human breast milk. • There were no effects on the breastfed infant. There are no data on famotidine effects on milk production.
11	Pregnancy	Use in Pregnancy	The estimated background risk for major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes.
12	Precautions	Is there any interaction between medication and alcohol?	No
13	Interaction	Is there any interaction with food?	No
14	Warnings and precautions	Warnings and precautions	• Central Nervous System (CNS) Adverse Reactions: Elderly patients and patients with renal impairment are at increased risk. Dose reduction is recommended. • Gastrointestinal (GI) Malignancy: Relief of GI symptoms does not rule out gastric malignancy. Evaluate patients before initiating therapy.
15	Storage	What are the storage conditions?	Store the dry powder at 25°C (77°F). It may be kept between 15°C and 30°C (59°F to 86°F) for short periods. Keep the bottle tightly closed and protected from light.
16	Dispensing	How to Dispense?	As prescribed by the Physician
17	Contraindication	What are the contraindications of (medication).	Famotidine for oral suspension is contraindicated in patients with a history of serious hypersensitivity reactions

			(e.g., anaphylaxis) to famotidine or other H-receptor antagonists.
Pharmaceutical Particulars			
18	Pharmaceutical Form	How is it supplied?	Famotidine for Oral Suspension is supplied as a white to off-white powder in a bottle. After it is mixed with water by a healthcare provider or pharmacist, it becomes a white to off-white liquid suspension with cherry, banana, and peppermint flavors. The prepared suspension contains 40 mg of famotidine in every 5 mL. The oral suspension is available in bottles of 55mL (NDC 72205-233-84)
19	Ingredients	Active and Inactive Ingredients	**Active:** Famotidine Oral Suspension **Inactive:** Citric Acid Monohydrate, Microcrystalline Cellulose 101, Sucrose, Xanthan Gum, Sodium Benzoate, Methylparaben Sodium and Propylparaben Sodium
20	Coating	What is the type of coating?	None
Allergens			
21	Ingredients	Is it Vegetarian?	yes
22	Ingredients	Does it contain Gluten?	No
23	Ingredients	Does it contain Dairy Products?	No
24	Ingredients	Does it contain Casein	No
25	Ingredients	Does it contain Whey?	No
26	Ingredients	Does it contain corn?	No
27	Ingredients	Does it contain rye?	No
28	Ingredients	Does it contain sugar?	No
29	Ingredients	Does it contain Oats?	No
30	Ingredients	Does it contain wheat?	No
31	Ingredients	Does it contain spelt?	No
32	Ingredients	Does it contain barley?	No
33	Ingredients	Does it contain rennet?	No
34	Ingredients	Does it contain starch?	No
35	Ingredients	Does it contain Iodine?	No
36	Ingredients	Does it contain latex?	No
37	Ingredients	Does it contain alcohol?	Yes (Isopropyl Alcohol is less than ICH limit i.e NMT 5000 ppm)
38	Ingredients	Does it contain dyes?	No

39	Ingredients	Does it contain flavor?	No
40	Ingredients	Does it contain Lactose?	No
41	Ingredients	Does it contain Nuts?	No
42	Ingredients	Does it contain Preservatives?	Yes (Methylparaben Propyylparaben Potassium Sorbate)
43	Ingredients	Does it contain Soy products?	No
44	Ingredients	Does it contain peanut?	No
45	Ingredients	Does it contain nickel?	No
Miscellaneous			
46	Miscellaneous	May I know the product availability?	Novadoz Pharmaceuticals products are only available through pharmacies, wholesalers, and other authorized distributors. See our ADR (authorized distributors of record) page at NovadozPharma.com to learn more about where to find our products.
47	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
48	Miscellaneous	Do you have any patient's assistance program?	Novadoz Pharmaceuticals does not offer patient assistance programs at this time. The company that produces the brand version of your product may or may not offer such a program. Please check for access & eligibility requirements with that company.
49	Miscellaneous	How do I report an adverse drug effect or reaction to Novadoz medication?	To report suspected adverse reactions, contact Novadoz Pharmaceuticals LLC at 1-855-668-2369 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
50	Miscellaneous	Why does my pharmacy that used to fill your generic formulation of a particular medicine, no longer fills my prescription with Novadoz formulation?	Please check with your pharmacy as to why your prescription is not a Novadoz Pharmaceuticals product. You may refer to NovadozPharma.com ADR (authorized distributor of record) page to learn where to find our products.
51	Miscellaneous	Manufacturer and Distributor	**MSN Pharmaceuticals Inc** Piscataway, NJ 08854 **Distributed by:** **Novadoz Pharmaceuticals LLC** Piscataway, NJ 08854-3714