NOVADOZ
AN MSN COMPANY

FAMOTIDINE TABLETS, USP 20 mg and 40 mg

S.No.	Category	Question	Answer
Clinical Particulars			
1. 1	Use/Indication	What is the product indicated for?	Famotidine is a histamine-2 (H2) receptor antagonist indicated for use in adult and pediatric patients weighing 40 kg or greater for the treatment of: • Active duodenal ulcer (DU) • Active gastric ulcer • Symptomatic nonerosive gastroesophageal reflux disease (GERD) • Erosive esophagitis due to GERD, diagnosed by biopsy ***In adults, it is also indicated for:*** • The treatment of pathological hypersecretory conditions (e.g., Zollinger-Ellison syndrome, multiple endocrine neoplasias) • The reduction of the risk of DU recurrence
2. 2	Dosage	What is the recommended dosage?	***Adult and Pediatric Patients (40 kg and greater):*** • Active DU: 40 mg once daily or 20 mg twice daily • Active Gastric Ulcer: 40 mg once daily • GERD: 20 mg twice daily • Erosive Esophagitis: 20 mg twice daily or 40 mg twice daily ***Adults:*** • Pathological Hypersecretory Conditions: 20 mg every 6 hours, adjusted to patient needs; maximum 160 mg every 6 hours • Risk Reduction of DU Recurrence: 20 mg once daily.
3.	Administration	How do I take it?	✓ Take famotidine tablets once daily before bedtime or twice daily, in the morning and before bedtime, as recommended. ✓ Famotidine tablets may be taken with or without food. ✓ Famotidine tablets may be given with antacids.
4.	Formulation	Can tablet be crushed?	Do not crush or chew the tablets

5.	Administration	Use in Pediatric Population	Famotidine 20 mg and 40 mg tablets are not recommended for use in pediatric patients weighing less than 40 kg, as these tablet strengths exceed the recommended dose for these patients. For pediatric patients weighing less than 40 kg, consider using another famotidine formulation (e.g., oral suspension or lower-dose tablet).
6.	Administration	Use in Geriatric Population	Use the lowest effective dose of famotidine for an elderly patient and monitor renal function.
7.	Mechanism	Mechanism of Action	Famotidine is a competitive inhibitor of histamine-2 (H_2) receptors. The primary clinically important pharmacologic activity of famotidine is inhibition of gastric secretion. Both the acid concentration and volume of gastric secretion are suppressed by famotidine, while changes in pepsin secretion are proportional to volume output.
8.	Warning	Warning	• ***Central Nervous System (CNS) Adverse Reactions:*** Elderly patients and patients with renal impairment are at increased risk; reduce the dosage. • ***GI Malignancy:*** The absence of GI symptoms does not preclude the presence of gastric malignancy; evaluate prior to initiating therapy.
9.	Lactation	Use in Lactation	▪ There are limited data available on the presence of famotidine in human breast milk. ▪ No effects were observed on the breastfed infant.
10.	Pregnancy	Use in Pregnancy	The estimated background risk for major birth defects and miscarriage in the indicated population is unknown. All pregnancies carry a background risk of birth defects, loss, or other adverse outcomes.
11.	Precautions	Is there any interaction between medication and alcohol?	NO
12.	Interaction	Is there any interaction with other medication?	*1.* ***Drugs Dependent on Gastric pH for Absorption:*** Systemic exposure of the concomitant drug may be significantly reduced, leading to a loss of efficacy. See full prescribing information for a list of interacting drugs. *2.* ***Tizanidine (CYP1A2 Substrate):*** Potential for substantial increases in blood concentrations of tizanidine, resulting in hypotension, bradycardia, or excessive drowsiness. Avoid concomitant use, if possible.
13.	Interaction	Is there any interaction with food?	NO
14.	Storage	What are the storage conditions?	**Store at** 20° to 25°C (68° to 77°F).
15.	Dispensing	How to Dispense?	Dispense in a USP tight, light-resistant container.
16.	Contraindication	What are the contraindications of (medication).	Famotidine tablets are contraindicated in patients with a history of serious hypersensitivity reactions (e.g., anaphylaxis) to famotidine or other histamine-2 (H2) receptor antagonists.
Pharmaceutical Particulars			

17.	Pharmaceutical Form	How is it supplied?	***Famotidine Tablets USP, 20 mg:*** • Light yellow to yellow, round, film-coated tablets debossed with "11" on one side and "plain" on the other side. • Bottles of 30: NDC 72205-145-30 • Bottles of 100: NDC 72205-145-91 • Bottles of 500: NDC 72205-145-05 • Bottles of 1,000: NDC 72205-145-99 ***Famotidine Tablets USP, 40 mg:*** • White, round, film-coated tablets debossed with "12" on one side and "plain" on the other side. • Bottles of 30: NDC 72205-146-30 • Bottles of 100: NDC 72205-146-91 • Bottles of 500: NDC 72205-146-05 • Bottles of 1,000: NDC 72205-146-99
18.	Ingredients	Active and Inactive Ingredients	**Active**: Famotidine **Inactive:** Microcrystalline cellulose 101, Starch, corn, Sodium starch glycolate Type A, Hydroxypropyl cellulose (110000 WAMW), magnesium stearate, hypromellose 2910 (6 MPA.S), titanium dioxide, ferric oxide yellow, microcrystalline cellulose 102.
Allergens			
19.	Ingredients	Is it Vegetarian?	yes
20.	Ingredients	Does it contain Gluten?	No
21.	Ingredients	Does it contain Dairy Products?	No
22.	Ingredients	Does it contain Casein	No
23.	Ingredients	Does it contain Whey?	No
24.	Ingredients	Does it contain corn?	Contains starch
25.	Ingredients	Does it contain rye?	No
26.	Ingredients	Does it contain sugar?	No
27.	Ingredients	Does it contain Oats?	No
28.	Ingredients	Does it contain wheat?	No
29.	Ingredients	Does it contain spelt?	No
30.	Ingredients	Does it contain barley?	No
31.	Ingredients	Does it contain rennet?	No

32.	Ingredients	Does it contain starch?	Yes
33.	Ingredients	Does it contain Iodine?	No
34.	Ingredients	Does it contain latex?	No
35.	Ingredients	Does it contain alcohol?	Yes; API contains solvents within the limits as per ICH
36.	Ingredients	Does it contain dyes?	No
37.	Ingredients	Does it contain flavor?	No
38.	Ingredients	Does it contain Lactose?	No
39.	Ingredients	Does it contain Nuts?	No
40.	Ingredients	Does it contain Preservatives?	No
41.	Ingredients	Does it contain Soy products?	No
42.	Ingredients	Does it contain peanut?	No
43.	Ingredients	Does it contain nickel?	No
Miscellaneous			
44.	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.
45.	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
46.	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.
47.	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.
48.	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.
49.	Miscellaneous	Manufacturer and Distributor	**Manufactured by:** MSN Laboratories Private Limited Telangana – 509 228, INDIA **Distributed by:** Novadoz Pharmaceuticals LLC Piscataway, NJ 08854-3714