ACID REDUCER MAXIMUM STRENGTH- famotodine tablet
Allegiant Health

---

445 - Acid Reducer Maximum Strength

Active ingredient(s)

Famotidine USP 20 mg

Purpose

Acid reducer

Use(s)

- relieves heartburn associated with acid indigestion and sour stomach
- prevents heartburn associated with acid indigestion and sour stomach brought on by eating or
  drinking certain food and beverages

Warnings

Allergy alert: Do not use if you are allergic to famotidine or other acid reducers

Do not use

- if you have trouble or pain swallowing food, vomiting with
  blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
- with other acid reducers

Ask a doctor before use if

you have

- had heartburn over 3 months. This may be a sign of a more serious
  condition.
- heartburn with lightheadedness, sweating, or dizziness
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms,
  neck or shoulders; or lightheadedness
- frequent chest pain
- frequent wheezing, particularly with heartburn
- explained weight loss
- nausea or vomiting
- stomach pain
- kidney disease

Ask a doctor or pharmacist before use if

you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.

Stop use and ask a doctor if

- your heartburn continues or worsens
- you need to take this product for more than 14 days

If pregnant or breastfeeding,

ask a health professional before use.

Keep out of reach of children

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

adults and children 12 years and over:

- to relieve symptoms, swallow 1 tablet with a glass of water. Do not chew.
- to prevent symptoms, swallow 1 tablet with a glass of water at any time from 10 to 60 minutes before eating food or drinking beverages that cause heartburn
- do not use more than 2 tablets in 24 hours

children under 12 years: ask a doctor

Other information

- read the directions and warnings before use
- do not use if imprinted safety seal under cap is broken or missing n store at 20°-25°C (68°-77°F)
- protect from moisture

Inactive ingredients

carnauba wax, corn starch, hydroxypropyl cellulose, hypromellose, iron oxide red, iron oxide yellow, magnesium stearate, microcrystalline cellulose, sodium starch glycolate, talc, titanium dioxide

Questions/Comments

Call 1-888-952-0050 Monday through Friday
9AM − 5PM EST

Principal Display Panel

Acid Reducer

ACID REDUCER MAXIMUM STRENGTH

famotodine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69168-445
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FAMOTIDINE (UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8)	FAMOTIDINE	20 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	yellow	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	T;11
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-445-32	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/31/2024	
2	NDC:69168-445-52	225 in 1 BOTTLE; Type 0: Not a Combination Product	10/31/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA215767	10/31/2024	

Labeler - Allegiant Health (079501930)

Revised: 10/2024 Allegiant Health