ACID REDUCER MAXIMUM STRENGTH- famotodine tablet
Allegiant Health

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443 - Acid Reducer Maximum Strength

Active ingredient(s)

Famotidine USP 20mg

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

- 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
- unexplained 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 15 to 60 minutes before eating food or drinking beverages that cause heartburn n 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
- store at 20°-25°C (68°-77°F)
- protect from moisture

Inactive ingredients

Hydroxypropyl cellulose, hypromellose, macrogol, magnesium stearate, microcrystalline cellulose, pre-gelatinized starch, sodium starch glycolate, talc, titanium dioxide, triacetin

Questions/Comments

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

Principal Display Panel

Famotidine Tablets, USP 20mg

ACID REDUCER MAXIMUM STRENGTH

famotodine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69168-443
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
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	white	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	V;15
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-443-32	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/15/2024	
2	NDC:69168-443-52	225 in 1 BOTTLE; Type 0: Not a Combination Product	01/15/2024	
3	NDC:69168-443-09	10 in 1 BLISTER PACK; Type 0: Not a Combination Product	02/29/2024	
4	NDC:69168-443-50	1 in 1 CARTON	03/05/2024	
4		50 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA215822	01/15/2024	

Labeler - Allegiant Health (079501930)

Revised: 1/2024

Allegiant Health