### 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**





### **Drug Facts**

Active ingredient in each tablet) Famotidine USP 20mg

Purpose cid reducer

heartburn associated with acid indigestion and sour stomach brought on by eating or drinking indigestion and sour stomach 

prevents relieves heartburn associated with acid certain food and beverages

# Drug Facts (continued on inside)

This product is not manufactured or distributed by Maximum Strength Pepcid AC®. Pepcid AC® is a Johnson & Johnson Consumer Inc., distributor of

LB2135 R1023A

Distributed by:
Allegiant Health
Deer Park, NY 11729

X0040DLHD3

HealthA2Z® Acid Red... to Acid Indigestion

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registered trademark of Johnson & Johnson

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worsens wou need to take this product for more than 14 days Stop use and ask a doctor if your heartburn continues or certain prescription drugs.

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## Orug Facts (continued)

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dizziness chest pain or shoulder sweating; pain spreading to arms, may be a sign of a more serious lightheadedness, sweating, or pain with shortness of breath; condition. 

heartburn with

neck or shoulders; or lightheadednes wheezing, particularly with heartburn ■ frequent chest pain
■ frequent

■ nausea or vomiting
■ stomach unexplained weight loss pain | | kidney disease

drug. Acid reducers may interact with use if you are taking a prescription

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If pregnant or breast-feeding, ask a overdose, get medical help or contact health professional before use. Keep out of reach of children. In case of

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Famotidine Tablets, USP 20mg

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protect from

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Other information = read

### REDUCER MAXIMUM STRENGTH ACID

adults and children 12 years and over.

**Directions** 

Orug Facts (continued)

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  | <b>Basis of Strength</b> | 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: 3WJQ0SDW1A)     |          |  |  |
| 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<br>Date | Marketing End<br>Date |
| 1         | NDC:69168-<br>443-32 | 100 in 1 BOTTLE; Type 0: Not a Combination Product      | 01/15/2024              |                       |
| 2         | NDC:69168-<br>443-52 | 225 in 1 BOTTLE; Type 0: Not a Combination Product      | 01/15/2024              |                       |
| 3         | NDC:69168-<br>443-09 | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | 02/29/2024              |                       |
| 4         | NDC:69168-<br>443-50 | 1 in 1 CARTON   | 03/05/2024              |                       |
| 4         |                      | 50 in 1 BOTTLE; Type 0: Not a Combination Product       |                         |                       |

| Marketing Information |   |                         |                       |
|-----------------------|---|-------------------------|-----------------------|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |
| ANDA                  | ANDA215822                                  | 01/15/2024              |                       |
|                       |   |                         |                       |

### Labeler - Allegiant Health (079501930)

Revised: 1/2024 Allegiant Health