

**ACID REDUCER ORIGINAL STRENGTH- famotidine tablet**  
**ACID REDUCER MAXIMUM STRENGTH- famotidine tablet**  
**Dr.Reddys Laboratories Inc.**

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**Dr.Reddy's Laboratories Limited**

**Active ingredient (in each tablet)**

Famotidine USP, 10 mg/20 mg

**Purpose**

Acid reducer

**Uses**

- 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
- 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 breast-feeding,**

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**

- **For Famotidine 10 mg:**
- 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
  - do not use more than 2 tablets in 24 hours
- children under 12 years: ask a doctor
- **For Famotidine 20 mg:**
- 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
- keep the carton. It contains important information.
- store at 20°-25°C (68°-77°F)
- protect from moisture and light

## **Inactive ingredients**

colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, synthetic red iron oxide (only in 10 mg), talc and titanium dioxide

## **Questions or comments?**

call **1-888-375-3784**

## **Tips For Managing Heartburn**

### **Tips for Managing Heartburn**

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach

- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking

Famotidine 20 mg Container Carton Label - 90s ct



Famotidine 10 mg Container Carton Label



## ACID REDUCER ORIGINAL STRENGTH

famotidine tablet

### Product Information

|                                |                |                           |                              |
|--------------------------------|----------------|---------------------------|------------------------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:43598-824(NDC:55111-118) |
| <b>Route of Administration</b> | ORAL           |                           |                              |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength |
|---|-------------------|----------|
| <b>FAMOTIDINE</b> (UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8) | FAMOTIDINE        | 10 mg    |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| <b>MAGNESIUM STEARATE</b> (UNII: 70097M6130)               |          |
| <b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)      |          |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)                  |          |
| <b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)                    |          |
| <b>STARCH, CORN</b> (UNII: O8232NY3SJ)                     |          |
| <b>Polyethylene Glycol, Unspecified</b> (UNII: 3WJQ05DW1A) |          |
| <b>TALC</b> (UNII: 7SEV7J4R1U)                             |          |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                 |          |

FERRIC OXIDE RED (UNII: 1K09F3G675)

### Product Characteristics

|          |       |              |          |
|----------|-------|--------------|----------|
| Color    | PINK  | Score        | no score |
| Shape    | ROUND | Size         | 6mm      |
| Flavor   |       | Imprint Code | C;118    |
| Contains |       |              |          |

### Packaging

| # | Item Code        | Package Description                                | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:43598-824-18 | 1 in 1 CARTON                                      | 09/01/2020           |                    |
| 1 |                  | 180 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               | ANDA077367                               | 09/01/2020           |                    |

## ACID REDUCER MAXIMUM STRENGTH

famotidine tablet

### Product Information

|                         |                |                    |                              |
|-------------------------|----------------|--------------------|------------------------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:43598-960(NDC:55111-396) |
| Route of Administration | ORAL           |                    |                              |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength |
|--|-------------------|----------|
| FAMOTIDINE (UNII: 5QZ015J2Z8) (FAMOTIDINE - UNII:5QZ015J2Z8) | FAMOTIDINE        | 20 mg    |

### Inactive Ingredients

| Ingredient Name                                     | Strength |
|---|----------|
| MAGNESIUM STEARATE (UNII: 70097M6130)               |          |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)      |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                  |          |
| HYPROMELLOSES (UNII: 3NXW29V3WO)                    |          |
| STARCH, CORN (UNII: O8232NY3SJ)                     |          |
| Polyethylene Glycol, Unspecified (UNII: 3WJQ0SDW1A) |          |
| TALC (UNII: 7SEV7J4R1U)                             |          |

**TITANIUM DIOXIDE** (UNII: 15FIX9V2JP)

### Product Characteristics

|                 |       |                     |          |
|-----------------|-------|---------------------|----------|
| <b>Color</b>    | WHITE | <b>Score</b>        | no score |
| <b>Shape</b>    | ROUND | <b>Size</b>         | 8mm      |
| <b>Flavor</b>   |       | <b>Imprint Code</b> | L1       |
| <b>Contains</b> |       |                     |          |

### Packaging

| # | Item Code        | Package Description                                | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:43598-960-65 | 1 in 1 CARTON                                      | 09/01/2020           |                    |
| 1 |                  | 65 in 1 BOTTLE; Type 0: Not a Combination Product  |                      |                    |
| 2 | NDC:43598-960-32 | 1 in 1 CARTON                                      | 09/01/2020           |                    |
| 2 |                  | 170 in 1 BOTTLE; Type 0: Not a Combination Product |                      |                    |
| 3 | NDC:43598-960-91 | 1 in 1 CARTON                                      | 10/07/2021           |                    |
| 3 |                  | 90 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               | ANDA077367                               | 09/01/2020           |                    |

**Labeler** - Dr.Reddys Laboratories Inc. (802315887)

Revised: 10/2021

Dr.Reddys Laboratories Inc.