

**FAMOTIDINE - famotidine tablet, film coated  
WALGREEN CO.**

-----

***Drug Facts***

***Active ingredient (in each tablet)***

Famotidine USP 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 (1-800-222-1222) right away.

## ***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
- keep the carton. It contains important information.
- store at 20° to 25°C (68° to 77°F)
- protect from moisture

## ***Inactive ingredients***

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

## ***Questions or comments?***

call **1-855-274-4122**

### **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

***JUST ONE TABLET* prevents and relieves heartburn due to acid indigestion brought on by eating and drinking certain foods and beverages.**

**Do not use if carton is open or if printed foil seal under bottle cap is open or torn.**

Distributed by:

WALGREEN CO.  
200 WILMOT RD., DEERFIELD, IL 60015  
**100% SATISFACTION GUARANTEED**  
walgreens.com © 2022 Walgreen Co.

### **MADE IN INDIA**

Code: TS/DRUGS/22/2009

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL -20 mg (200 Tablets, Container Label)**

***Walgreens***

**NDC 0363-5300-34**

**Acid Controller  
FAMOTIDINE TABLETS USP, 20 mg /  
ACID REDUCER**

**Maximum Strength**

- Just one tablet prevents & relieves





## FAMOTIDINE

famotidine tablet, film coated

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:0363-5300 |
| <b>Route of Administration</b> | ORAL           |                           |               |

**Active Ingredient/Active Moiety**

| <b>Ingredient Name</b>  | <b>Basis of Strength</b> | <b>Strength</b> |
|---|--------------------------|-----------------|
| <b>FAMOTIDINE</b> (UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8) | FAMOTIDINE               | 20 mg           |

**Inactive Ingredients**

| <b>Ingredient Name</b>  | <b>Strength</b> |
|---|-----------------|
| <b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)                          |                 |
| <b>STARCH, CORN</b> (UNII: O8232NY3SJ)                          |                 |
| <b>HYDROXYPROPYL CELLULOSE (160000 WAMW)</b> (UNII: RFW2ET671P) |                 |
| <b>HYPROMELLOSE 2910 (5 MPA.S)</b> (UNII: R75537T0T4)           |                 |
| <b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)                    |                 |
| <b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)            |                 |
| <b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)                      |                 |
| <b>SODIUM STARCH GLYCOLATE TYPE A CORN</b> (UNII: AG9B65PV6B)   |                 |
| <b>TALC</b> (UNII: 7SEV7J4R1U)                                  |                 |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                      |                 |
| <b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)                   |                 |

**Product Characteristics**

|                 |                                |                     |          |
|-----------------|--------------------------------|---------------------|----------|
| <b>Color</b>    | YELLOW                         | <b>Score</b>        | no score |
| <b>Shape</b>    | ROUND (Square shaped Biconvex) | <b>Size</b>         | 5mm      |
| <b>Flavor</b>   |                                | <b>Imprint Code</b> | CC;59    |
| <b>Contains</b> |                                |                     |          |

**Packaging**

| <b>#</b> | <b>Item Code</b> | <b>Package Description</b>                         | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|----------|------------------|--|-----------------------------|---------------------------|
| 1        | NDC:0363-5300-53 | 1 in 1 CARTON                                      | 04/26/2016                  |                           |
| 1        |                  | 25 in 1 BOTTLE; Type 0: Not a Combination Product  |                             |                           |
| 2        | NDC:0363-5300-14 | 1 in 1 CARTON                                      | 04/26/2016                  |                           |
| 2        |                  | 50 in 1 BOTTLE; Type 0: Not a Combination Product  |                             |                           |
| 3        | NDC:0363-5300-50 | 1 in 1 CARTON                                      | 04/26/2016                  |                           |
| 3        |                  | 85 in 1 BOTTLE; Type 0: Not a Combination Product  |                             |                           |
| 4        | NDC:0363-5300-34 | 1 in 1 CARTON                                      | 07/26/2022                  |                           |
| 4        |                  | 200 in 1 BOTTLE; Type 0: Not a Combination Product |                             |                           |
| 5        | NDC:0363-5300-47 | 1 in 1 CARTON                                      | 02/17/2024                  |                           |
| 5        |                  | 75 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               | ANDA206531                               | 04/26/2016           |                    |

**Labeler** - WALGREEN CO. (008965063)

**Registrant** - Aurohealth LLC (078728447)

## Establishment

| Name                   | Address | ID/FEI    | Business Operations                          |
|------------------------|---------|-----------|--|
| APL HEALTHCARE LIMITED |         | 650844777 | ANALYSIS(0363-5300) , MANUFACTURE(0363-5300) |

## Establishment

| Name                     | Address | ID/FEI    | Business Operations                          |
|--------------------------|---------|-----------|--|
| Aurobindo Pharma Limited |         | 650381903 | ANALYSIS(0363-5300) , MANUFACTURE(0363-5300) |

Revised: 4/2025

WALGREEN CO.