

**FAMOTIDINE - famotidine tablet, film coated**  
**Aurohealth LLC**

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***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:

**AUROHEALTH LLC**

279 Princeton-Hightstown Road  
East Windsor, NJ 08520

Made in India

Code: TS/DRUGS/22/2009

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL -20 mg (85 Tablets, Container Label)**

NDC 58602-829-50

**PrimaryHealth**

See New Warnings

**Acid Reducer**

**MAXIMUM STRENGTH**

Famotidine

Tablets USP 20 mg

***Just One Tablet!***

Prevents & Relieves Heartburn  
Due to Acid Indigestion

**85 Tablets**



PrimaryHealth

NDC 58602-829-50

See New Warnings

**Acid Reducer**  
**MAXIMUM STRENGTH**  
Famotidine  
Tablets USP 20 mg

**Just One Tablet!**  
Prevents & Relieves Heartburn  
Due to Acid Indigestion

**85 Tablets**

**Do not use if printed foil seal on bottle is broken or missing.**

**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 **lightheadiness, 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** See carton for complete list of inactive ingredients

**Questions or comments?** call 1-855-274-4122  
Distributed by: **AUROHEALTH LLC**  
279 Princeton-Hightstown Road  
East Windsor, NJ 08520  
Made in India Code: TSD/DRUGS/22/2009

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LOT

EXP

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL -20 mg (85 Tablets, Container Carton Label)**

NDC 58602-829-50

**PrimaryHealth**

**\*COMPARE TO** Maximum

Strength Pepcid® AC

Active Ingredient

**See New Warnings**

**MAXIMUM STRENGTH**

**Acid Reducer**

Famotidine

Tablets USP 20 mg

**Just One Tablet!**

Prevents & Relieves

Heartburn Due to

Acid Indigestion

Actual Size

**85 Tablets**



## FAMOTIDINE

famotidine tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58602-829
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

Ingredient Name	Strength
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>HYDROXYPROPYL CELLULOSE (1600000 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

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-829-21	1 in 1 CARTON	04/26/2016	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-829-50	1 in 1 CARTON	03/02/2021	
2		85 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:58602-829-34	1 in 1 CARTON	03/25/2021	
3		200 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** - Aurohealth LLC (078728447)

## Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	ANALYSIS(58602-829) , MANUFACTURE(58602-829)

## Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(58602-829) , MANUFACTURE(58602-829)

Revised: 4/2025

Aurohealth LLC