

FAMOTIDINE - famotidine tablet, film coated
Aurohealth LLC

Drug Facts

Active ingredient (in each tablet)

Famotidine USP 10 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 **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

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 and titanium dioxide.

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 -10 mg (90 Tablets Container Label)

AUROHEALTH

NDC 58602-705-19

ORIGINAL STRENGTH

Famotidine

Tablets USP 10 mg

Acid Reducer

Just One Tablet!

*Prevents & Relieves Heartburn
Due to Acid Indigestion*

90 Tablets



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL -10 mg, Blister Carton 30 Tablets
AUROHEALTH

NDC 58602-705-09

***Compare to the Active
Ingredient of Original
Strength Pepcid® AC
ORIGINAL STRENGTH
Famotidine
Tablets USP
10 mg**

***Acid Reducer
Just One Tablet!***

*Prevents & Relieves Heartburn
Due to Acid Indigestion*

30 Tablets

LEBG809S3

Drug Facts

Active Ingredient (in each tablet)	Purpose
Famotidine USP 10 mg	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.

Drug Facts (continued)
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 15 to 60 minutes before eating food or drinking beverages that cause heartburn
■ do not use more than 2 tablets in 24 hours
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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 and titanium dioxide.

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 the individual blister seal is open or torn.

Distributed by:
AUROHEALTH LLC
279 Princeton-Hightstown Road,
East Windsor, NJ 08520

Made in India
Code: TS/DRUGS/22/2009

N
3158602705091

Left
EXP-1

The product
Container Has

AUROHEALTH

NDC 58602-705-09
*Compare to the Active
Ingredient of Original

Acid Reducer
Just One Tablet!

AURIC



Labeling Format Information:	
Font type :	Helvetica Condensed
Barline :	2.5 pt
Hairline :	0.5 pt
Drug facts :	9 pt
Drug facts (continued):	8 pt
Header :	7 pt
Subheader :	6 pt
Leading :	0.5 pt
Body text :	6 pt
Bullets :	5 pt

FAMOTIDINE

famotidine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-705
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FAMOTIDINE (UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8)	FAMOTIDINE	10 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	PINK	Score	no score
Shape	ROUND (biconvex)	Size	5mm
Flavor		Imprint Code	CC;58
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-705-15	1 in 1 CARTON	04/26/2016	
1		60 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-705-19	1 in 1 CARTON	04/26/2016	
2		90 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:58602-705-84	1 in 1 CARTON	05/13/2019	
3		30 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:58602-705-09	3 in 1 CARTON	04/26/2016	
4	NDC:58602-705-03	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:58602-705-12	4 in 1 CARTON	04/26/2016	
5	NDC:58602-705-03	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:58602-705-93	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/26/2016	
7	NDC:58602-705-14	1 in 1 CARTON	12/21/2019	
7		50 in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:58602-705-34	1 in 1 CARTON	07/22/2020	

8		200 in 1 BOTTLE; Type 0: Not a Combination Product		
9	NDC:58602-705-39	1 in 1 CARTON	07/22/2020	
9		365 in 1 BOTTLE; Type 0: Not a Combination Product		
10	NDC:58602-705-44	1 in 1 CARTON	07/22/2020	
10		400 in 1 BOTTLE; Type 0: Not a Combination Product		
11	NDC:58602-705-40	1 in 1 CARTON	07/22/2020	
11		500 in 1 BOTTLE; Type 0: Not a Combination Product		
12	NDC:58602-705-88	1 in 1 CARTON	07/22/2020	
12		750 in 1 BOTTLE; Type 0: Not a Combination Product		
13	NDC:58602-705-41	1 in 1 CARTON	09/04/2020	
13		1000 in 1 BOTTLE; Type 0: Not a Combination Product		
14	NDC:58602-705-32	1 in 1 CARTON	02/18/2022	
14		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	ANDA206531	04/26/2016	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(58602-705) , MANUFACTURE(58602-705)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	ANALYSIS(58602-705) , MANUFACTURE(58602-705)

Revised: 3/2025

Aurohealth LLC