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

Labeling Format Information:	
Font type :	Helvetica Condensed
Drug facts :	NA
Drug facts (continued):	NA
Header :	4.5 pt
Subheader :	4 pt
Leading :	0.5 pt
Body text :	4 pt
Bullets :	3.5 pt
Barline	NA

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL -10 mg (90 Tablets Container Carton Label)

AUROHEALTH
NDC 58602-705-19

***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

90 Tablets

Labeling Format Information:	
Font type :	Helvetica Condensed
Burline	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

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

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
APL HEALTHCARE LIMITED		650844777	ANALYSIS(58602-705) , MANUFACTURE(58602-705)

Establishment

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