FAMOTIDINE - famotidine tablet, film coated
Aurohealth LLC

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
2572 Brunswick Pike
Lawrenceville, NJ 08648

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

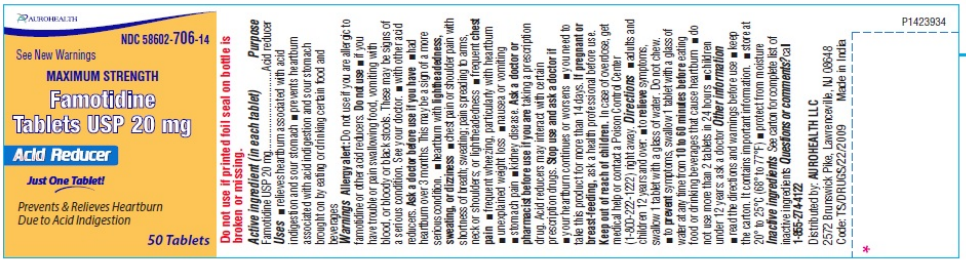
PACKAGE LABEL-PRINCIPAL DISPLAY PANEL -20 mg (50 Tablets, Container Label)

AUROHEALTH
NDC 58602-706-14
See New Warnings
MAXIMUM STRENGTH
Famotidine
Tablets USP 20 mg

Acid Reducer
Just One Tablet!

Prevents & Relieves Heartburn
Due to Acid Indigestion

50 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 -20 mg (50 Tablets, Container Carton Label)

AUROHEALTH

NDC 58602-706-14
*Compare to the Active Ingredient
of Maximum Strength **Pepcid® AC**
MAXIMUM STRENGTH

Famotidine
Tablets USP
20 mg

Acid Reducer
Just One Tablet!

Prevents & Relieves Heartburn
Due to Acid Indigestion

50 Tablets

Labeling Format Information:	
Font type :	Helvetica Condensed
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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 -20 mg Blister Carton 25 Tablets

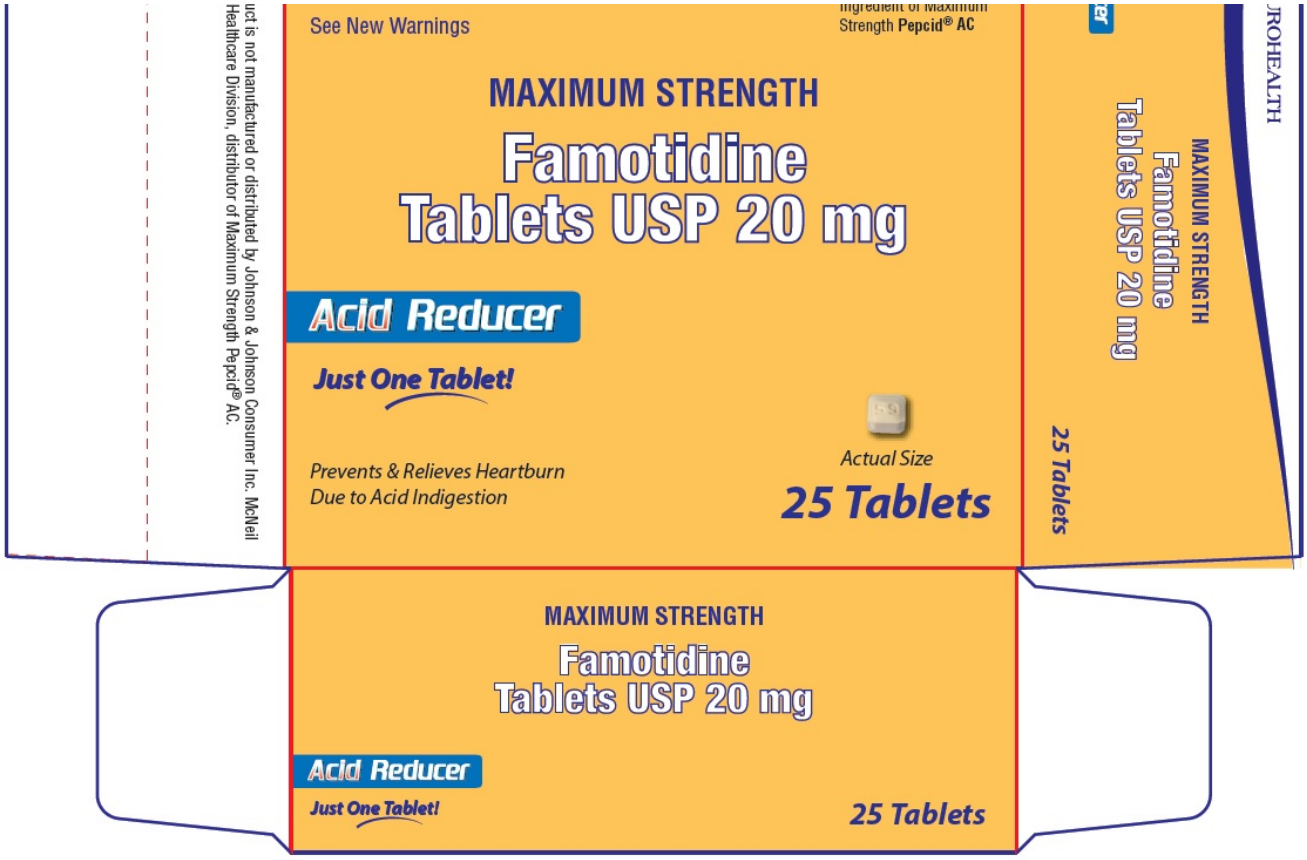
AUROHEALTH

NDC 58602-706-62
*Compare to the Active
Ingredient of Maximum
Strength **Pepcid® AC**
MAXIMUM STRENGTH
Famotidine
Tablets USP
20 mg

Acid Reducer
Just One Tablet!

Prevents & Relieves Heartburn
Due to Acid Indigestion

25 Tablets



Labeling Format Information:	
Font type :	Helvetica Condensed
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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:58602-706
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FAMOTIDINE (UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8)	FAMOTIDINE	20 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)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	YELLOW	**Score**	no score
Shape	ROUND (Square shaped Biconvex)	**Size**	5mm
Flavor		**Imprint Code**	CC;59
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-706-53	1 in 1 CARTON	04/26/2016	
1		25 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-706-56	1 in 1 CARTON	04/26/2016	
2		35 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:58602-706-14	1 in 1 CARTON	04/26/2016	
3		50 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:58602-706-16	1 in 1 CARTON	04/26/2016	
4		65 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:58602-706-54	1 in 1 CARTON	04/26/2016	
5		70 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:58602-706-47	1 in 1 CARTON	04/26/2016	
6		75 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:58602-706-18	1 in 1 CARTON	04/26/2016	
7		80 in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:58602-706-50	1 in 1 CARTON	04/26/2016	
8		85 in 1 BOTTLE; Type 0: Not a Combination Product		
9	NDC:58602-706-21	1 in 1 CARTON	04/26/2016	
9		100 in 1 BOTTLE; Type 0: Not a Combination Product		
10	NDC:58602-706-62	5 in 1 CARTON	04/26/2016	
10	NDC:58602-706-60	5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
11	NDC:58602-706-94	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/26/2016	
12	NDC:58602-706-79	1 in 1 CARTON	04/26/2016	
12		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
13	NDC:58602-706-15	2 in 1 CARTON	02/24/2020	

13		8 in 1 BLISTER PACK; 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(58602-706) , MANUFACTURE(58602-706)

Revised: 2/2020 Aurohealth LLC