

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

2572 Brunswick Pike

Lawrenceville, NJ 08648

Made in India

Code: TS/DRUGS/22/2009

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

NDC 58602-828-19

PrimaryHealth

See New Warnings

Acid Reducer

ORIGINAL STRENGTH

Famotidine

Tablets USP 10 mg

Just One Tablet!

Prevents & Relieves Heartburn
Due to Acid Indigestion

90 Tablets

NDC 58602-828-19



See New Warnings

Acid Reducer
ORIGINAL STRENGTH
Famotidine
Tablets USP 10 mg

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

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

Purpose
Famotidine USP, 10 mg, is a H₂ receptor antagonist. 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 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 heart burn 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 ■ 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 before use ■ keep the cap on. 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: AIROHEALTH LLC
2572 Brunswick Pike, Lawrenceville, NJ 08648
Made in India Code: TS/DRUS/22/2009

P1425413 LH-3785

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* Lot: XXXXXXXX
EXP: MM/YYYY
Prefix & Variables of Lot, EXP shall be printed online during packing.

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

NDC 58602-828-19
PrimaryHealth

***COMPARE TO Original
Strength Pepcid® AC
Active Ingredient**
See New Warnings
Acid Reducer
ORIGINAL STRENGTH
Famotidine
Tablets USP 10 mg

Just One Tablet!

Prevents & Relieves
Heartburn Due to
Acid Indigestion

Actual Size

90 Tablets



FAMOTIDINE

famotidine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-828
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:58602-828-19	1 in 1 CARTON	04/26/2016	
1		90 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(58602-828) , MANUFACTURE(58602-828)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	ANALYSIS(58602-828) , MANUFACTURE(58602-828)