

**FAMOTIDINE - famotidine tablet, film coated**  
**Magno-Humphries, Inc.**

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**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

## **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
- 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 **1-800-935-6737**

## **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 printed foil seal under bottle cap is open or torn.**

Distributed by:

**Magno-Humphries Labs**

Tigard, OR 97223, U.S.A.

**Visit our website: [www.magno-humphries.com](http://www.magno-humphries.com)**

Made in India

Code: TS/DRUGS/22/2009

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

**MHL®**

\*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**



**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 printed foil seal under bottle is broken or torn.**

**Lift Here For Drug Facts**

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GR011-990-01-0 P1416155

<b>Drug Facts</b>	<b>Active Ingredient Purpose (in each tablet)</b> Famotidine USP 10 mg..... Acid Reducer	<b>Uses</b> relieves heartburn associated with acid indigestion and sour stomach. prevents heartburn associated with acid indigestion and sour stomach by blocking the action of certain foods and beverages.	<b>Warnings</b> <b>Allergy alert:</b> Do not use if you are allergic to any of the ingredients or other acid reducers. <b>Do not use</b> 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. <b>Ask a doctor before use</b> 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; spreading to arms, neck or shoulders; or lightheadedness frequent wheezing, particularly with heartburn increased weight loss nausea or vomiting stomach pain <b>Stop use and ask a doctor if</b> your heartburn continues or worsens you need to take this product for more than 14 days <b>If pregnant or breast-feeding,</b> ask a health care professional before use. <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. <b>Directions</b> adults and children 12 years and over: swallow 1 tablet with a glass of water. Do not chew. to prevent heartburn: take 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 capsules in 24 hours. Ask your doctor 12 years ask a doctor.	<b>Other information</b> read the directions and warnings before use. Store at 20°C to 25°C (68° to 77°F). protect from moisture.
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<b>Drug Facts (continued)</b>	<b>Inactive Ingredients</b> corn starch, hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, red iron oxide, sodium starch glycolate, talc and titanium dioxide.	<b>Questions or comments?</b> call 1-800-955-6737
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**Tips for Managing Heartburn**

- Do not lie flat or bend over after eating. Do not wear tight-fitting clothing around the waist.
- Stop eating or drinking before bedtime.
- Raise the head of your bed.
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol, and tomatoes.
- Vegetables eat slowly and avoid big meals.
- If overweight, lose weight.
- Quit smoking.

\*This product is not manufactured or distributed by Johnson & Johnson • MERCK Consumer Health Products, Inc. or its distributor of Original Strength Papco® AG. Made in India Code: TS-DRUGS22009

# FAMOTIDINE

famotidine tablet, film coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54257-180
<b>Route of Administration</b>	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

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

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54257-180-07	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/26/2016	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206531	04/26/2016	

**Labeler** - Magno-Humphries, Inc. (063251433)

**Registrant** - Aurohealth LLC (078728447)

## Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	ANALYSIS(54257-180) , MANUFACTURE(54257-180)

## Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(54257-180) , MANUFACTURE(54257-180)

Revised: 5/2025

Magno-Humphries, Inc.