

**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 cap is open or torn.**

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Visit our website: [www.magno-humphries.com](http://www.magno-humphries.com)  
GR011-990-01-0 P1416155

Lift Here For Drug Facts

<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 relieves acid indigestion and sour stomach associated with eating or drinking certain food 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 • Headache • Rash • Spreading to arms, neck or shoulders • or frequent chest pain • frequent wheezing, particularly with heartburn • unexplained 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: • to relieve symptoms, swallow 1 tablet with a glass of water. Do not chew. • to prevent heartburn, 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 capsules in 24 hours • ask your doctor 12 years ask a doctor
<b>Other information</b>	<ul style="list-style-type: none"> <li>read the directions and warnings</li> <li>store at controlled room temperature (68° to 77° F) (20° to 25° C)</li> <li>protect from moisture</li> </ul>		

<b>Drug Facts (continued)</b>	<b>Inactive Ingredients</b> Famotidine USP 10 mg, starch, hydroxypropyl cellulose, hypromellose, magnesium stearate, 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 at least 3 hours 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.
- Stop eating 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 Division  
distributor of Original Strength Papcap® AC.  
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 (160000 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: 12/2021

Magno-Humphries, Inc.