

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

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.
- if you have kidney disease, except under the advice and supervision of a 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 **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
- 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 **1-800-935-6737**

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

Made in India

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL -20 mg (100 Tablets, Container Label)

MHL®

*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**

100 TABLETS



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68020-100-01-0

Lift Here For Drug Facts

LM-2077

Drug Facts	Active Ingredient Purpose (in each tablet) Famotidine USP 20 mg..... Acid reducer
Uses	relieves heartburn associated with acid indigestion and sour stomach • prevents heartburn associated with acid indigestion and sour stomach • prevents 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	• 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 right away • you have kidney disease except under the advice and supervision of a doctor • with other acid reducers
Ask a doctor before use if you have	• had heartburn over 12 years and over • signs or symptoms of a condition • heartburn with lightheadedness, sweating, or dizziness • chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck, or jaw • frequent chest pain • frequent wheezing, particularly with heartburn • unexplained weight loss • nausea or vomiting • stomach pain
Stop use and ask a doctor if you have	• your heartburn continues or worsens • you need to take this product for more than 14 days
If pregnant or breast-feeding, ask health professional before use.	
Keep out of reach of children. 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 heartburn, swallow 1 tablet with a glass of water at any time from eating food or drinking beverages that cause heartburn • do not use more than 2 tablets in 24 hours • ask your doctor 12 years; ask a doctor
Other information	read the directions and warnings carefully • store at 20° to 25° C

Drug Facts (continued)	See the back of the box for more information
Inactive Ingredients	croscarmellose sodium, hydroxypropyl cellulose, bromelain, magnesium stearate, microcrystalline cellulose, red iron oxide, sodium starch glycolate, talc, titanium dioxide and yellow iron oxide.
Questions or comments?	call 1-800-326-5737

The Ice Managing Heartburn

- Do not lie flat or bend over after eating • Do not wear tight 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 greasy foods, citrus fruits, caffeine, alcohol, and certain fruits and vegetables • Eat slowly • Avoid carbonated beverages • If overweight, lose weight • Quit smoking

*This product is not intended to be distributed by Johnson & Johnson • NERCK Consumer Products Co. distributor of Maximum Strength Pepacid® AC. Made in India

FAMOTIDINE

famotidine tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54257-802
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 (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)		
FERRIC OXIDE YELLOW (UNII: EX43802MRT)		

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:54257-802-02	100 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(54257-802) , MANUFACTURE(54257-802)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(54257-802) , MANUFACTURE(54257-802)

Revised: 12/2021

Magno-Humphries, Inc.