FAMOTIDINE- famotidine tablet, film coated Proficient Rx LP

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

Repackaged by:

Proficient Rx LP

Thousand Oaks, CA 91320

Code: TS/DRUGS/22/2009

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL -10 mg (30 Tablets Container Label)

NDC 71205-637-30 See New Warnings *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

30 Tablets





NDC 71205-637-30

Packaged By: Proficient Rx LP Thousand Oaks, CA 91320

Famotidine 10mg #30 Tablets Lot #:00000 #30 NDC 71205-637-30

SN# MASTER Exp:00/00/00

Famotidine 10mg #30 Tablets Lot #:00000 NDC 71205-637-30

SN# MASTER Exp:00/00/00

#30 Tal Tablets NDC 71205-637-30

SN# MASTER Exp:00/00/00

Famotidine 10mg

GTIN: 00371205637309 SN# MASTER Exp. 00/00/00 Lot #:00000

Famotidine 10mg

#30 **Tablets**

Each tablet contains: Famotidine USP 10 mg Acid Reducer

Pink, round, biconvex tablets with imprint code 'CC' and '58'

Product ID: QF063730

Dist. By: AUROHEALTH LLC 2572 Brunswick Pike, Lawrenceville, NJ 08648 Made in India Store at 20° to 25°C (68° to 77°F)

Keep medication out of the reach of children

FAMOTIDINE

famotidine tablet, film coated

Product Informat

Product Type HUMAN OTC DRUG Item Code (Source) NDC:71205-637(NDC:58602-705)

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: 15FIX9V2IP)

Product Characteristics

PINK Color 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:71205-637- 30	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/03/2022	
2	NDC:71205-637- 60	60 in 1 BOTTLE; Type 0: Not a Combination Product	02/03/2022	
3	NDC:71205-637- 90	90 in 1 BOTTLE; Type 0: Not a Combination Product	02/03/2022	

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

Labeler - Proficient Rx LP (079196022)

Establishment				
Name	Address	ID/FEI	Business Operations	
Proficient Rx LP		079196022	REPACK(71205-637), RELABEL(71205-637)	

Revised: 6/2022 Proficient Rx LP