# FAMOTIDINE- famotidine tablet, film coated Proficient Rx LP

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## **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.
- 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 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
- 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, titanium dioxide and yellow iron oxide.

#### 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**

279 Princeton-Hightstown Road, East Windsor, NJ 08520

Made in India

Code: TS/DRUGS/22/200

Repackaged by:

**Proficient Rx LP** 

Thousand Oaks, CA 91320

# PACKAGE LABEL-PRINCIPAL DISPLAY PANEL -20 mg (90 Tablets, Container Label)

NDC 71205-663-90

\*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

90 Tablets





NDC 71205-663-90

Packaged By: Proficient Rx LP Thousand Oaks, CA 91320

Famotidine 20mg #90 Tablets Lot #:00000 NDC 71205-663-90

SN# MASTER Exp:00/00/00

Famotidine 20mg #90 Tablets Lot #:00000 NDC 71205-663-90

SN# MASTER Exp:00/00/00

Famotidine 20mg Tablets Lot #:00000

SN# MASTER Exp:00/00/00

NDC 71205-663-90



GTIN: 00371205663902 SN# MASTER Exp. 00/00/00 Lot #:00000

## Famotidine 20mg

#90 **Tablets** 

Each tablet contains: Famotidine USP 20 mg Acid reducer

Yellow, round (square shaped biconvex) tablets with imprint code 'CC' and '59'

Product ID: QF066390

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 Information**

HUMAN OTC DRUG NDC:71205-663(NDC:58602-706) **Product Type Item Code (Source)** 

**Route of Administration ORAL** 

## **Active Ingredient/Active Moiety**

**Ingredient Name Basis of Strength** Strength **FAMOTIDINE** FAMOTIDINE (UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8) 20 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)	
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:71205-663- 30	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/24/2022	
2	NDC:71205-663- 60	60 in 1 BOTTLE; Type 0: Not a Combination Product	05/24/2022	
3	NDC:71205-663- 90	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/24/2022	

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(71205-663), RELABEL(71205-663)

Revised: 5/2022 Proficient Rx LP