

FAMOTIDINE - famotidine tablet, film coated
Amerisource Bergen

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
AmerisourceBergen
1 West First Avenue
Conshohocken, PA 19428
Questions or Concerns?**

www.mygnp.com

Made in India
Code: TS/DRUGS/22/2009

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL -20 mg (25 Tablets, Container Label)

**GOOD
NEIGHBOR
PHARMACY®**

NDC 46122-737-63

**Famotidine Tablets USP
20 mg
Acid Reducer
*Maximum Strength***

Just One Tablet!
Prevents & Relieves **Heartburn**
Due to Acid Indigestion

25 Tablets

GOOD NEIGHBOR PHARMACY® NDC 46122-737-63

Famotidine Tablets USP 20 mg
Acid Reducer
Maximum Strength

Just One Tablet!
Prevents & Relieves Heartburn
Due to Acid Indigestion

25 Tablets

Do not use if printed foil seal on bottle is broken or missing.

Active ingredient (in each tablet) Purpose
Famotidine USP 20 mg.....Acid reducer

Uses ■relieves heartburn associated with acid indigestion and sour stomach ■prevents heartburn brought on by eating or drinking certain food and beverages ■relieves heartburn associated with acid indigestion and sour stomach

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 a hard 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** See carton for complete list of inactive ingredients. See **Questions or comments?** call 1-855-274-4172

Distributed By
AmerisourceBergien
1 West First Avenue
Conshohocken, PA 19028
Questions or Concerns?
www.myngp.com Code: TS/DRUGS/22/2009

Made in India

P.1 #3 1978 I.M - 5081

*Lat:XXXXXXXX
EXP: MM/YYYY
Prefix & Variables of Lot, EXP shall be printed online during packing.



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL -20 mg (25 Tablets, Container Carton Label)

GOOD NEIGHBOR PHARMACY®

***Compare to the active ingredient in Maximum Strength Pepcid® AC NDC 46122-737-63**

Famotidine Tablets USP 20 mg Acid Reducer Maximum Strength

Just One Tablet!
Prevents & Relieves **Heartburn**
Due to Acid Indigestion

actual size

25 Tablets

25 Tablets

Acid Reducer
Famotidine Tablets USP 20 mg

GOOD NEIGHBOR PHARMACY®

Acid Reducer
Famotidine Tablets USP 20 mg
Maximum Strength

Just One Tablet!
Prevents & Relieves Heartburn
Due to Acid Indigestion

25 Tablets

Compare to the active ingredient in Maximum Strength Pepcid® AC NDC 46122-737-63

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Made in India

GLUE - NO COATING
GLUE - NO COATING
glue b2q
glue b2q

EXP: 10/2019

NDC 46122-737-63

LR-3074

nc

FAMOTIDINE

famotidine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46122-737
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 (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: EX438O2MRT)	

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:46122-737-63	1 in 1 CARTON	07/20/2023	

1		25 in 1 BOTTLE; Type 0: Not a Combination Product	
2	NDC:46122-737-71	1 in 1 CARTON	07/20/2023
2		50 in 1 BOTTLE; Type 0: Not a Combination Product	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206531	07/20/2023	

Labeler - Amerisource Bergen (007914906)

Registrant - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	ANALYSIS(46122-737) , MANUFACTURE(46122-737)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(46122-737) , MANUFACTURE(46122-737)

Revised: 3/2024

Amerisource Bergen