

FAMOTIDINE - famotidine tablet, film coated
Fred's, 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
- 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: Fred's Inc
4300 New Getwell Road
Memphis, TN 38118
www.fredsinc.com**

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

***Fred's
Pharmacy***

**NDC 55315-435-53
MAXIMUM STRENGTH
Acid Reducer
Famotidine
Tablets USP 20 mg**

Just One Tablet!

**Prevents & Relieves
Heartburn Due to
Acid Indigestion**

25 Tablets

fred's Pharmacy NDC 55315-435-53

MAXIMUM STRENGTH
Acid Reducer
 Famotidine
 Tablets USP 20 mg
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)
 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 blood, 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 light-headedness, sweating, or dizziness ■ chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or light-headedness ■ 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 you have heartburn, 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 carton, 2530 689 80747 ■ product from moisture

Inactive ingredients See carton for complete list of inactive ingredients.

Questions or comments? call 1-855-274-4172

Distributed by: Fred's Inc., 4900 New Getwell Road
 Memphis, TN 38118. www.fredsmc.com
 Made in India Code: 15DRUGS272609

01161W1

* Lot: XXXXXXXXX
 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)

fred's Pharmacy

NDC 55315-435-53

*Compare to the Active Ingredient in:
 Maximum Strength **Pepcid® AC**

MAXIMUM STRENGTH
Acid Reducer
Famotidine
Tablets USP 20 mg

Just One Tablet!

Prevents & Relieves
Heartburn Due to
Acid Indigestion

25 Tablets



FAMOTIDINE

famotidine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55315-435
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FAMOTIDINE (UNII: 5QZ015J2Z8) (FAMOTIDINE - UNII:5QZ015J2Z8)	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:55315-435-53	1 in 1 CARTON	04/26/2016	
1		25 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	04/26/2016	

Labeler - Fred's, Inc. (005866116)

Registrant - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	ANALYSIS(55315-435) , MANUFACTURE(55315-435)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(55315-435) , MANUFACTURE(55315-435)

Revised: 12/2021

Fred's, Inc.