

FAMOTIDINE- famotidine tablet, film coated
Fred's Inc.

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

- with other acid reducers
- 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.

Ask a doctor before use if you have

- frequent **chest pain**
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain
- 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

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 right away (1-800-222-1222).

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 **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

- store at 20° to 25°C (68° to 77°F)
- protect from moisture
- read the directions and warnings before use
- keep the carton. It contains important information.
- **TAMPER EVIDENT: DO NOT USE IF THE CARTON OR INDIVIDUAL BLISTER UNIT IS OPEN OR TORN.**

INACTIVE INGREDIENTS

Colloidal silicon dioxide, hydroxypropyl cellulose, hypromellose, iron oxide red, magnesium stearate, microcrystalline cellulose, polyethylene glycol 400, pregelatinized starch, talc, titanium dioxide

QUESTIONS?

Call **1-800-406-7984**

PATIENT INFORMATION

- **1 tablet** relieves heartburn due to acid indigestion
- Famotidine prevents heartburn due to acid indigestion brought on by eating and drinking certain foods and beverages.

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

PRINCIPAL DISPLAY PANEL

fred's[®]

Original Strength

Acid Controller

Famotidine Tablets USP, 10 mg

Acid Reducer

Just One Tablet

Prevents & Relieves Heartburn Due to Acid Indigestion

30 TABLETS

Compare To Original Strength Pepcid® AC†

DISTRIBUTED BY: fred's, Inc.

5092839/R0112



5092839

Drug Facts

Active ingredient (in each tablet)
Famotidine USP, 10 mg
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
■ with other acid reducers
■ 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.
Ask a doctor before use if you have
■ frequent chest pain ■ frequent wheezing, particularly with heartburn ■ unexplained weight loss
■ nausea or vomiting ■ stomach pain
■ 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

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 right away (1-800-222-1222).

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 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



5092839



8

0 184579 11902

fred's Promise
Not Happy With This Product?
Just Bring It Back For a Refund!

RO112

DISTRIBUTED BY: fred's, Inc.
4300 NEW GETWELL RD, MEMPHIS, TN 38118
www.fredsinc.com

- 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

fred's®

Original Strength

Acid Controller

fred's®

Original Strength

Shown at Actual Size

Acid Controller
Famotidine Tablets
USP, 10 mg
Acid Reducer
Just One Tablet
Prevents & Relieves Heartburn
Due to Acid Indigestion
30 TABLETS

fred's LAB TESTED
Lab Tested for Quality, Fred Tested for Satisfaction

Compare To
Original Strength
Pepcid® AC†

†This product is not manufactured or distributed by Johnson & Johnson • Merck Consumer Pharmaceuticals Co., distributor of Pepcid® AC. Pepcid® AC is a registered trademark of Merck & Co., Inc.

TAMPER EVIDENT: DO NOT USE IF THE CARTON OR INDIVIDUAL BLISTER UNIT IS OPEN OR TORN.

Expiration Date:

Batch No.

Non Varnish Area

Drug Facts (continued)

Other information
■ store at 20° to 25° C (68° to 77° F)
■ keep the carton, it contains important information.
■ protect from moisture
■ read the directions and warnings before use

Inactive ingredients colloidal silicon dioxide, hydroxypropyl cellulose, hypromellose, iron oxide red, magnesium stearate, microcrystalline cellulose, polyethylene glycol 400, pregelatinized starch, talc, titanium dioxide

Questions? call 1-800-406-7984

See end panel for batch number and expiration date.

■ 1 tablet relieves heartburn due to acid indigestion
■ Famotidine prevents heartburn due to acid indigestion brought on by eating and drinking certain foods and beverages.

FAMOTIDINE

famotidine tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55315-035
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
COLLOIDAL SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	pink	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	035
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55315-035-31	30 in 1 BLISTER PACK		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090283	06/25/2010	

Labeler - Fred's Inc. (005866116)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(55315-035)

Revised: 1/2013

Fred's Inc.