

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

- with other acid reducers
- if you have kidney disease, except under the advice and supervision of a doctor.
- 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 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

- store at 20° to 25°C (68° to 77°F)
- protect from moisture
- read the directions and warnings before use
- **TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL IS BROKEN OR MISSING FROM BOTTLE.**

INACTIVE INGREDIENTS

Colloidal silicon dioxide, hydroxypropyl cellulose, hypromellose, 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

GOOD NEIGHBOR PHARMACY®

NDC 46122-0168-78

Compare to the active ingredient of Maximum Strength Pepcid® AC

famotidine tablets USP, 20 mg

Acid Reducer

Maximum Strength

Just One Tablet
Prevents & Relieves Heartburn
Due to Acid Indigestion
100 tablets
Distributed By: AmerisourceBergen
5098331/R0812



INSIDE TOP

Drug Facts (continued)

- 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 5 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 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

BASE

Drug Facts (continued)

Other information ■ store at 20° to 25° C (68° to 77° F) ■ protect from moisture ■ read the directions and warnings before use

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

Questions? call 1-800-406-7388 ■ 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.

Tip for Managing Heartburn ■ Do not eat fat or food over after eating. ■ Do not wear tight-fitting clothing around the stomach. ■ Do not eat before bedtime. ■ Rise to the end 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. ■ Avoid weight, low weight. ■ Quit smoking.

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FAMOTIDINE

famotidine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46 122-168
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
COLLOIDAL SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D6IU)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	036
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46122-168-78	100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090283	07/23/2010	

Labeler - Amerisource Bergen (007914906)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(46122-168)

Revised: 10/2012

Amerisource Bergen