

**FAMOTIDINE- famotidine tablet, film coated**  
**Kinray**

-----

**Drug Facts**

**ACTIVE INGREDIENT (IN EACH TABLET)**

Famotidine USP, 10 mg

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**

**Famotidine USP, 10 mg**

- 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.

**Famotidine USP, 20 mg**

- 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**

### **Famotidine USP, 10 mg**

- 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

### **Famotidine USP, 20 mg**

- 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
- keep the carton. It contains important information.
- **TAMPER EVIDENT: DO NOT USE IF THE CARTON OR INDIVIDUAL BLISTER UNIT IS OPEN OR TORN.**
- **TAMPER EVIDENT: DO NOT USE IF THE CARTON OR PRINTED FOIL UNDER CAP IS OPEN OR TORN.**

## **INACTIVE INGREDIENTS**

Colloidal silicon dioxide, hydroxypropyl cellulose, hypromellose, iron oxide red (only for Famotidine USP, 10 mg), 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**

**Preferred Plus Pharmacy™**

†Compare to the active ingredient of Original Strength Pepcid® AC

### **ORIGINAL STRENGTH**

**Acid Controller**

**Famotidine Tablets USP, 10 mg**

**Acid Reducer**

**Just One Tablet**

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

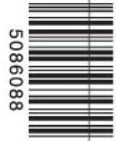
**30 Tablets**

**Distributed By: Kinray, Inc.**

**5086088/0411**



8909805



5086088

**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

†Compare to the active ingredient of Original Strength Pepcid® AC

**Preferred plus Pharmacy™**

**ORIGINAL STRENGTH**

# Acid Controller

**Famotidine Tablets USP, 10 mg**

**30 TABLETS** Acid Reducer

†Compare to the active ingredient of Original Strength Pepcid® AC

**Preferred plus Pharmacy™**

**ORIGINAL STRENGTH**

# Acid Controller

**Famotidine Tablets USP, 10 mg**

**Acid Reducer**

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

**30 TABLETS**

**SATISFACTORY GUARANTEED**

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

Expiration Date: \_\_\_\_\_  
Batch No. \_\_\_\_\_

Non Varnish Area



3 516601 03531 5

0411

**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.

This product is not manufactured or distributed by Johnson & Johnson - Merck Consumer Pharmaceuticals Co., a subsidiary of Johnson & Johnson, Inc. (Peppid® AC is a registered trademark of Johnson & Johnson, Inc.).

Distributed by: Kinney Inc., Whitehouse, NY 11987

All Preferred Plus Pharmacy products are substances manufactured or your pharmacy which have been purchased from a wholesaler or your retailer where purchased.

Manufactured by: Orlin Laboratories Inc., 1385 Livingston Avenue, North Brunswick, NJ 08902

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

**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

■ 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.

See end panel for batch number and expiration date.

**Preferred Plus Pharmacy™**

†Compare to the active ingredient of Maximum Strength Pepcid® AC

**MAXIMUM STRENGTH**

**Acid Controller**

**Famotidine Tablets USP, 20 mg**

**Acid Reducer**

**Just One Tablet**

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

**25 Tablets**

**Distributed By: Kinray, Inc.**

**5091314/1111**

†Compare to the active ingredient of Maximum Strength Pepcid® AC



MAXIMUM STRENGTH

# Acid Controller

## Famotidine Tablets USP, 20 mg

25 TABLETS

Acid Reducer



MAXIMUM STRENGTH

# Acid Controller

## Famotidine Tablets USP, 20 mg

Acid Reducer

25 TABLETS



Just One Tablet Prevents & Relieves Heartburn Due to Acid Indigestion



†Compare to the active ingredient of Maximum Strength Pepcid® AC

- 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

Expiration Date:

NON VARNISH

Batch No.

**TAMPER EVIDENT: DO NOT USE IF THE CARTON OR PRINTED FOIL UNDER CAP IS OPEN OR TORN.**  
See end panel for batch number and expiration date.

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.



3

5 1660 03626 8

1111

(© 2011 Keney Inc. All Rights Reserved. PREPARED BY: PREFERRED PLUS PHARMACY, INC. A subsidiary of Keney Inc. All other marks are property of their respective owners.  
Distributed by: Keney Inc., Whitehouse, NY 11957  
All Preferred Plus Pharmacy products are satisfaction guaranteed or your money back from retailer where purchased.  
Manufactured by: Olin Laboratories, Inc. 1365 Livingston Avenue, North Brunswick, NJ 08902

- 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.

**Questions?** call 1-800-406-7984

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

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

**Other information**

**Drug Facts (continued)**

- 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

**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).

**Stop use and ask a doctor if**

- your heartburn continues or worsens
- you need to take this product for more than 14 days

- Ask a doctor before use if you have**
- unexplained weight loss
  - stomach pain
  - nausea or vomiting
  - 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

- Do not use**
- with other acid reducers
  - if you have kidney disease, except under the advice and supervision of a doctor
  - signs of a serious condition. See your doctor.

**Warnings**

**Allergy alert:** Do not use if you are allergic to famotidine or other acid reducers

**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

5091314



5091314



**Drug Facts**  
 Active ingredient (in each tablet)  
 Famotidine USP, 20 mg  
 Purpose  
 Acid reducer

# FAMOTIDINE

famotidine tablet, film coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61715-063
<b>Route of Administration</b>	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

<b>Color</b>	pink	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	8mm
<b>Flavor</b>		<b>Imprint Code</b>	035
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61715-063-30	1 in 1 CARTON		
1		30 in 1 BLISTER PACK		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

ANDA	ANDA090283	10/03/2011	
------	------------	------------	--

## FAMOTIDINE

famotidine tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61715-064
<b>Route of Administration</b>	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)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)	
MAGNESIUM STEARATE (UNII: 70097M6B30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	8mm
<b>Flavor</b>		<b>Imprint Code</b>	036
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61715-064-25	1 in 1 CARTON		
1		25 in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090283	02/15/2012	



**Labeler** - Kinray (012574513)

**Registrant** - Ranbaxy Pharmaceuticals Inc. (937890044)

**Establishment**

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(61715-063, 61715-064)

Revised: 6/2013

Kinray