

FAMOTIDINE- famotidine tablet, film coated
Chain Drug Marketing Association Inc.

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 - 10 mg Tablet Blister Pack Carton

QUALITY[®]
CHOICE

NDC 63868-714-30

†Compare to
Active Ingredient in
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

5111684



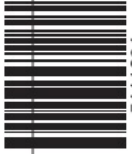
Drug Facts
(in each tablet)
Famotidine, USP 10 mg Acid reducer

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

Drug Facts (continued)
■ 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



5111684



Acid Controller

Famotidine Tablets, USP 10 mg



NDC 63868-714-30

'Compare to
Active Ingredient in
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

- Tips for Managing Heartburn**
- Do not lie flat or bend over after eating
 - Do not eat before bedtime
 - Eat slowly and avoid big meals
 - Do not wear tight-fitting clothing around the stomach
 - 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
 - If overweight, lose weight
 - Quit smoking

Expiration Date:

Batch No.

Non Varnish Area

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

See end panel for batch number and expiration date.

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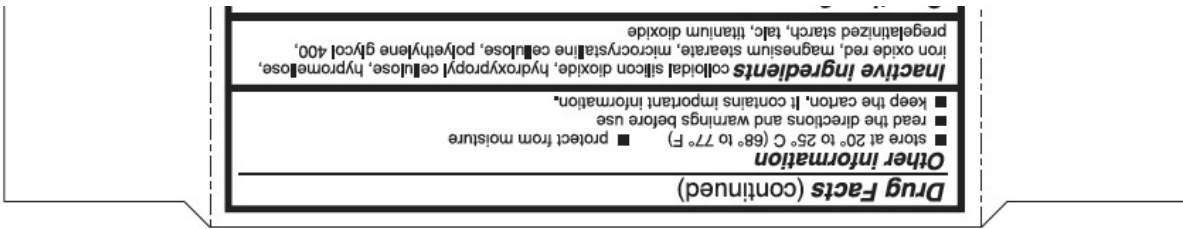


100% SATISFACTION GUARANTEED

Distributed by C.D.M.A., Inc.®
43157 W. Nine Mile
Novi, MI 48376-0995
www.qualitychoice.com
Questions: 248-449-9300

R0914

JUST ONE TABLET prevents and relieves heartburn due to acid indigestion brought on by eating and drinking certain foods and beverages. Questions? call 1-800-406-7984



PRINCIPAL DISPLAY PANEL - 20 mg Tablet Bottle Carton

NDC 63868-486-25

QUALITY®
CHOICE

†Compare to
Active Ingredient in
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



Acid Controller

Famotidine Tablets, USP 20 mg

NDC 63868-486-25



Compare to Active Ingredient in 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

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

Batch No.

NON VARNISH

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Questions: 248-448-9300

R0914

JUST ONE TABLET prevents and relieves heartburn due to acid indigestion brought on by eating and drinking certain foods and beverages.

Questions? call 1-800-406-7984

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

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

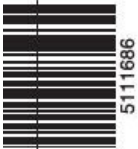
Other Information

Drug Facts (continued)

- 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
- 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
- nausea or vomiting
- unexplained weight loss

- 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
- 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).
- 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

Directions



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Drug Facts
 (in each tablet)
Active ingredient
Purpose
 ■ stomach pain
 ■ had heartburn over 3 months. This may be

FAMOTIDINE

famotidine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-714
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYDROXYPROPYL CELLULOSE (1200000 MW) (UNII: RFW2ET671P)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
STARCH, 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:63868-714-30	30 in 1 BLISTER PACK; Type 0: Not a Combination Product	06/25/2010	

Marketing Information

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

famotidine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-486
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYDROXYPROPYL CELLULOSE (1200000 MW) (UNII: RFW2ET671P)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
STARCH, 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:63868-486-25	25 in 1 BOTTLE; Type 0: Not a Combination Product	07/23/2010	
2	NDC:63868-486-50	50 in 1 BOTTLE; Type 0: Not a Combination Product	07/23/2010	

Marketing Information

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

Labeler - Chain Drug Marketing Association Inc. (011920774)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(63868-714, 63868-486)

Revised: 8/2018

Chain Drug Marketing Association Inc.