

FAMOTIDINE- famotidine tablet
Chain Drug Marketing Association INC

Dr.Reddy's Laboratories Limited

Active ingredient (in each tablet)

Famotidine USP, 10 mg/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.
- 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
- kidney disease

Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.

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

- **For Famotidine 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 at any time from **15 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
- **For Famotidine 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

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

Inactive ingredients

colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, synthetic red iron oxide (only in 10 mg), talc and titanium dioxide

Questions or comments?

call **1-888-375-3784**


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

Famotidine 10 mg

Container Label



**Maximum Strength
Famotidine
Tablets USP, 20 mg**

Acid Reducer


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

25 Tablets

NDC 63868-584-25

TAMPER EVIDENT: DO NOT USE IF FOIL SEAL UNDER CAP PRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING

Drug Facts
Active ingredient (in each tablet) Famotidine USP 20 mg
Purpose Acid reducer USP ■ 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. ■ 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 light-headedness ■ frequent chest pain ■ frequent wheezing, particularly with heartburn ■ unexplained weight loss ■ nausea or vomiting ■ stomach pain ■ kidney disease
Other information ■ Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs. 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 ■ read the directions and warnings before use ■ Keep the carton. It contains important information. ■ store at 20°-25°C (68°-77°F) ■ protect from moisture ■ **inactive ingredients** colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, talc and titanium dioxide
Questions? call 1-888-375-3784



Distributed by C.D.M.A., Inc.®
43157 W 9 Mile Rd
Novi, MI 48375
www.qualitychoice.com
Questions: 800-935-2362


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REV 09/20

Famotidine 10 mg Container Carton Label



**Maximum Strength
Famotidine
Tablets USP, 20 mg**

Acid Reducer

NDC 63868-584-25

Compare to the active ingredient in Maximum Strength Pepcid AC™

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- 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 or beverages

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

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

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Tablets USP, 20 mg**

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Famotidine 20 mg
Container Label

NDC 63868-584-25

QC QUALITY CHOICE

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Famotidine
Tablets USP, 20 mg
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■ adults and children 12 years and over:
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Compare to the active ingredient in Maximum Strength Pepcid AC[®]

Maximum Strength Famotidine Tablets USP, 20 mg Acid Reducer

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- Do not eat before bedtime
- Raise the head of your bed
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- Eat slowly and avoid big meals
- If overweight, lose weight
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"This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of Maximum Strength Pepcid AC[®]. Pepcid AC[®] is a registered trademark of Johnson & Johnson.

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Famotidine 20 mg Container Carton Label

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QC QUALITY CHOICE

Maximum Strength
Famotidine
Tablets USP, 20 mg
Acid Reducer

NDC 63868-584-25

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FAMOTIDINE
famotidine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-583(NDC:55111-118)
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
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
STARCH, CORN (UNII: O8232NY3SJ)	
Polyethylene Glycol, Unspecified (UNII: 3WJQ0SDW1A)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Product Characteristics

Color	PINK	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	C;118
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-583-30	1 in 1 CARTON	12/01/2020	
1		30 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	ANDA077367	12/01/2020	

FAMOTIDINE

famotidine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-584(NDC:55111-396)
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
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
STARCH, CORN (UNII: O8232NY3SJ)	
Polyethylene Glycol, Unspecified (UNII: 3WJQ0SDW1A)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	L1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-584-25	1 in 1 CARTON	12/01/2020	
1		25 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:63868-584-50	1 in 1 CARTON	12/01/2020	
2		50 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	ANDA077367	12/01/2020	

Revised: 10/2024

Chain Drug Marketing Association INC