

**FAMOTIDINE- famotidine tablet**  
**Chain Drug Marketing Association INC**

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**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** ■ 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

**150081768**

LOT

EXP

Made in India  
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™**

Drug Facts	Purpose
<b>Active ingredient (in each tablet)</b> Famotidine USP, 20 mg	Acid reducer
<b>Uses</b>	■ 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
<b>Warnings</b>	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

**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

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

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

**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



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

**Acid Reducer**

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

**25 Tablets**

Made in India  
REV 09/20



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**150081768**

LOT

EXP

Famotidine 20 mg  
Container Label



NDC 63868-584-25

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

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

**25 Tablets**

**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  
**Uses**  
■ relieves heartburn associated with acid indigestion and sour stomach  
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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 tightness, 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

**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**  
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■ store at 20°-25°C (68°-77°F)  
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**Questions?** call 1-888-375-3784

Made in India  
REV 09/20

150081768

LOT  
EXP

Famotidine 20 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<sup>®</sup>**

Drug Facts	Purpose
<b>Active ingredient (in each tablet)</b> Famotidine USP, 20 mg	Acid reducer
<b>Uses</b> ■ 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	
<b>Warnings</b> <b>Allergy alert:</b> 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 tightness, 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	

**Drug Facts (continued)**  
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:  
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**Other information**  
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■ protect from moisture

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**Questions?** call 1-888-375-3784

**Tips for Managing Heartburn**

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- Do not wear tight-fitting clothing around the stomach
- 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
- Quit smoking

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

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

\*This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of Maximum Strength Pepcid AC<sup>®</sup>. Pepcid AC<sup>®</sup> is a registered trademark of Johnson & Johnson.

25 Tablets





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Made in India  
REV 09/20



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LOT  
EXP

Made in India  
REV 09/20

**FAMOTIDINE**  
famotidine tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63868-583(NDC:55111-118)
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>FAMOTIDINE</b> (UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8)	FAMOTIDINE	10 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>Polyethylene Glycol, Unspecified</b> (UNII: 3WJQ0SDW1A)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	

## Product Characteristics

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

## 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

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA077367	12/01/2020	

## FAMOTIDINE

famotidine tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63868-584(NDC:55111-396)
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>FAMOTIDINE</b> (UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8)	FAMOTIDINE	20 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>Polyethylene Glycol, Unspecified</b> (UNII: 3WJQ0SDW1A)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## 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>	L1
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA077367	12/01/2020	

Revised: 7/2025

Chain Drug Marketing Association INC