#### FAMOTIDINE- famotidine tablet Family Dollar Stores, 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?**

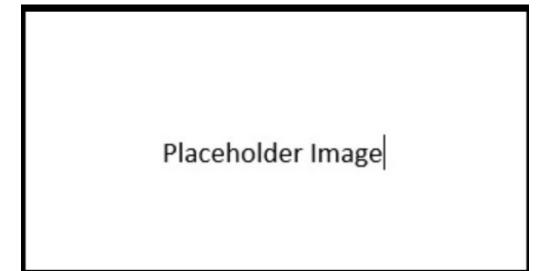
call 1-888-375-3784

# 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

# PACKAGE LABEL PRINCIPAL DISPLAY PANEL SECTION



# Placeholder Image

<b>FAMOTIDINE</b> famotidine tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55319-426
Route of Administration	ORAL		

Active Ingred	ient/Act	ive Moiety					
	In	gredient Name	Basis of S	Strength	Strength		
FAMOTIDINE (UNI	: 5QZO15J2	2Z8) (FAMOTIDINE - U	JNII:5QZ015J2Z8)	FAMOTIDINE		10 mg	
Inactive Ingre	edients						
	Julento	Ingredien	t Name		c	trength	
MAGNESIUM STE	ARATE (LINI	-	c Name			uengui	
		LLINE (UNII: OP1R32	2D61U)				
SILICON DIOXIDE							
HYPROMELLOSES							
STARCH, CORN (L							
		cified (UNII: 3WQ05	SDW1A)				
TALC (UNII: 7SEV7)	· ·						
TITANIUM DIOXID	E (UNII: 15	FIX9V2JP)					
FERRIC OXIDE RE	<b>D</b> (UNII: 1K	09F3G675)					
Product Char	acterist	ics					
Color		PINK	Score		no score		
Shape		ROUND	Size	6mm			
Flavor			Imprint Code		C;118		
Contains							
<b>.</b>							
Packaging							
# Item Code		Package Descr	iption	Marketing Start Date		eting End Date	
<b>1</b> NDC:55319-426- 60				10/01/2023			
1	60 in 1 BOTTLE; Type 0: Not a Combination Product						
Marketing	Inform	nation					
		plication Number or Monograph Citation		Marketing Star Date	rt Mark	eting End	
Marketing Category		Citatio	n	Dutt		Date	
Marketing	ANDA0		n	11/01/2021		Date	

FAMOTIDINE						
famotidine tablet						
Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55319-427			
Route of Administration	ORAL					

		ive Moiety						
	In	Ingredient Name				Strength	Strength	
FAMOTIDINE (UN	UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8)				FAMOTIDINE		20 mg	
Inactive Ing	redients							
		Ingrea	dient Name			S	Strength	
MAGNESIUM STI	EARATE (UNI	II: 70097M6I30)						
CELLULOSE, MIG	ROCRYSTA	LLINE (UNII: OF	P1R32D61U)					
SILICON DIOXID	<b>E</b> (UNII: ETJ72	Z6XBU4)						
HYPROMELLOSE	<b>S</b> (UNII: 3NX)	W29V3WO)						
STARCH, CORN		-						
Polyethylene Gl		cified (UNII: 3)	MJQ0SDW1A)					
TALC (UNII: 7SEV	-							
TITANIUM DIOXI	<b>DE</b> (UNII: 156	FIX9V2JP)						
Dwa dwat Cha								
	Characteristics							
Color		WHITE				no score 8mm		
Shape		ROUND Size						
				_				
Flavor			Imprint Cod	e		L1		
Flavor Contains				e				
				e				
Contains				e				
Contains Packaging		Package Do	Imprint Cod		eting Start Date	L1 Marke	eting End Date	
Contains Packaging # Item Code		Package Do	Imprint Cod		Date	L1 Marke	-	
Contains Packaging # Item Code 1 NDC:55319-42	<sup>7-</sup> 1 in 1 CA	Package Do	Imprint Cod	Mark	Date	L1 Marke	-	
Contains Packaging # Item Code 1 NDC:55319-42 1	<ul> <li><sup>7-</sup> 1 in 1 CAF</li> <li>25 in 1 BO</li> <li>Product</li> <li><sup>7-</sup> 1 in 1 CAF</li> </ul>	Package Do RTON OTTLE; Type 0: RTON	Imprint Cod escription	Mark	<b>Date</b> 23	L1 Marke	-	
Contains Packaging Item Code I NDC:55319-42 2 NDC:55319-42 2 NDC:55319-42 2	<ul> <li>7- 1 in 1 CAR</li> <li>25 in 1 BC</li> <li>Product</li> <li>7- 1 in 1 CAR</li> <li>50 in 1 BC</li> <li>Product</li> </ul>	Package Do RTON OTTLE; Type 0: RTON	Imprint Cod	<b>Mark</b> 10/01/20	<b>Date</b> 23	L1 Marke	-	
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Contains Packaging Item Code I NDC:55319-42 2 NDC:55319-42 2 I NDC:55319-42 3 NDC:55319-42	<ul> <li>7- 1 in 1 CAP</li> <li>25 in 1 BQ</li> <li>Product</li> <li>7- 1 in 1 CAP</li> <li>50 in 1 BQ</li> <li>Product</li> <li>7- 1 in 1 CAP</li> <li>100 in 1 E</li> </ul>	Package Do RTON OTTLE; Type 0: RTON OTTLE; Type 0: RTON	escription Not a Combination Not a Combination	Mark 10/01/20 10/01/20	<b>Date</b> 23 23	L1 Marke	-	
Contains Packaging Item Code Item Co	<ul> <li>7- 1 in 1 CAP</li> <li>25 in 1 BC</li> <li>Product</li> <li>7- 1 in 1 CAP</li> <li>50 in 1 BC</li> <li>Product</li> <li>7- 1 in 1 CAP</li> <li>100 in 1 E</li> <li>Product</li> </ul>	Package Do RTON OTTLE; Type 0: RTON OTTLE; Type 0: RTON BOTTLE; Type 0	escription Not a Combination Not a Combination	Mark 10/01/20 10/01/20	<b>Date</b> 23 23	L1 Marke	-	

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
ANDA	ANDA077367	11/01/2021	

Labeler - Family Dollar Stores, Inc. (024472631)

Revised: 6/2023