FAMOTIDINE- famotidine tablet
Dr.Reddys Laboratories Limited

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**

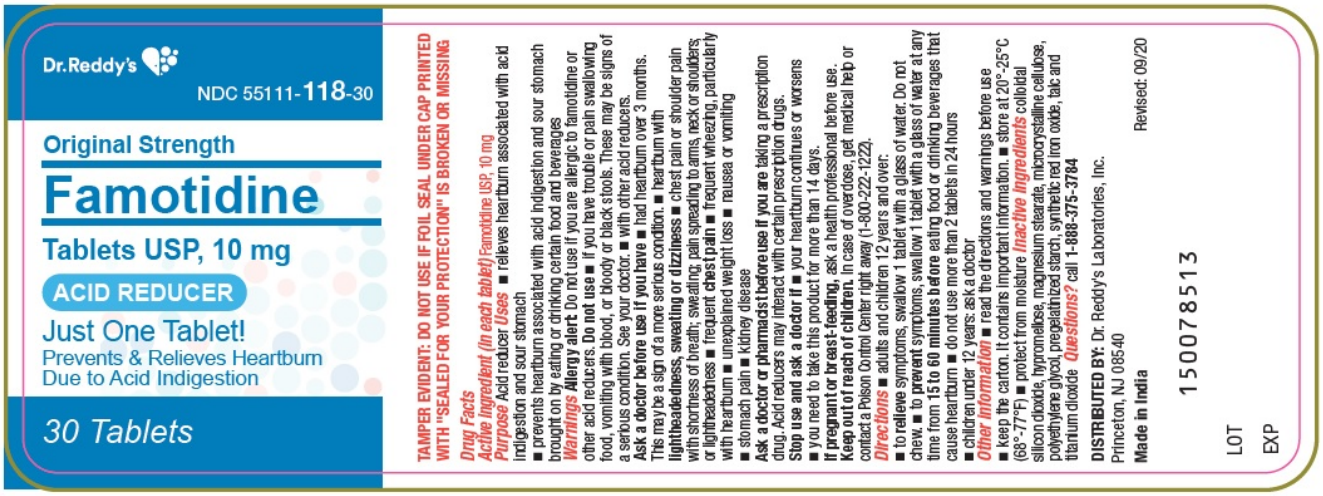
Tips for Managing Heartburn

- 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

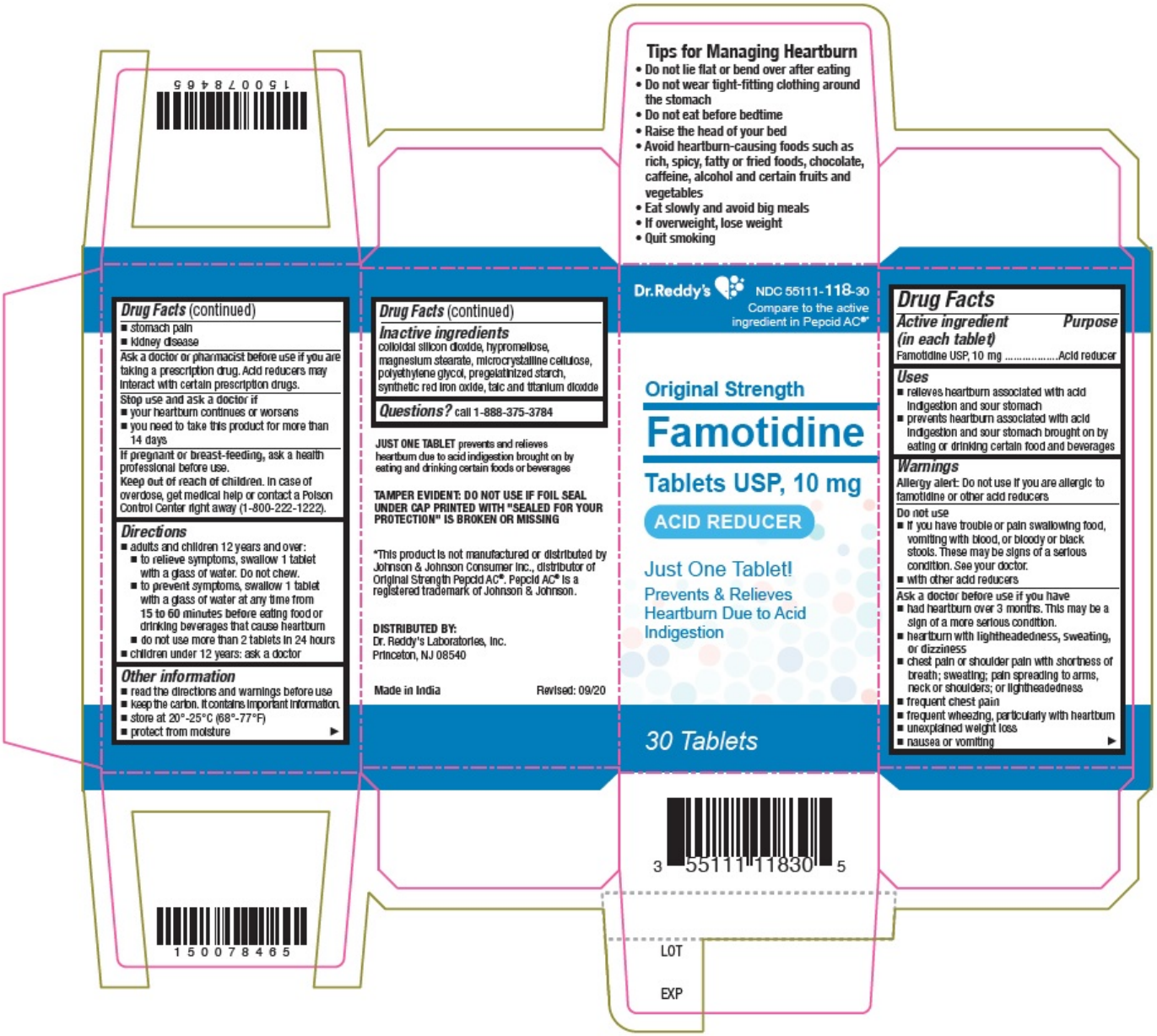
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking

Famotidine 10 mg

Container Label

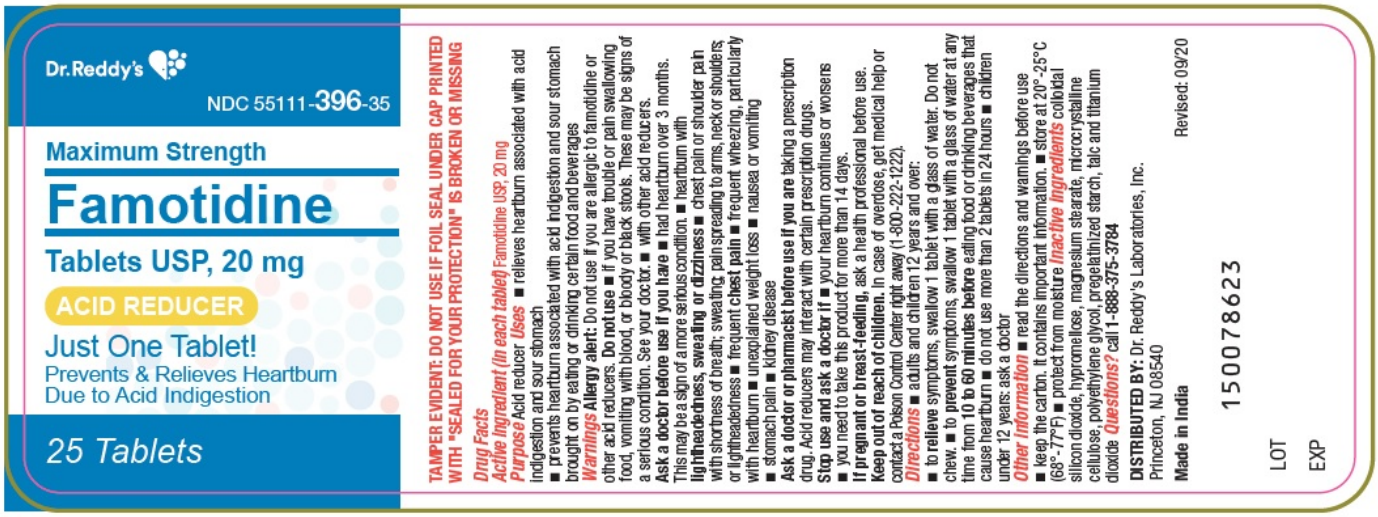


Container Carton Label



Famotidine 20 mg

Container Label



Container Carton Label

FAMOTIDINE

famotidine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	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: 3WQ0SDW1A)	
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:55111-118-30	1 in 1 CARTON	09/30/2006	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:55111-118-40	1 in 1 CARTON	10/01/2020	
2		40 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:55111-118-60	1 in 1 CARTON	09/30/2006	
3		60 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:55111-118-90	1 in 1 CARTON	09/30/2006	
4		90 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:55111-118-04	1 in 1 CARTON	10/01/2020	
5		120 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:55111-118-18	1 in 1 CARTON	09/30/2006	
6		180 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:55111-118-24	4 in 1 CARTON	09/30/2006	
7		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
8	NDC:55111-118-35	3 in 1 CARTON	09/30/2006	
8		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		

9	NDC:55111-118-81	3 in 1 CARTON	09/30/2006	
9		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
10	NDC:55111-118-79	1 in 1 CARTON	09/30/2006	
10		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
11	NDC:55111-118-12	1 in 1 CARTON	09/30/2006	
11		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077367	09/30/2006	

FAMOTIDINE

famotidine tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	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: 3WQ0SDW1A)	
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:55111-396-35	1 in 1 CARTON	09/30/2006	
1		25 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:55111-396-50	1 in 1 CARTON	09/30/2006	
2		50 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:55111-396-65	1 in 1 CARTON	10/01/2020	
3		65 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:55111-396-90	1 in 1 CARTON	10/07/2021	
4		90 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:55111-396-44	2 in 1 CARTON	09/30/2006	
5	NDC:55111-396-01	100 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:55111-396-13	1 in 1 CARTON	10/01/2020	
6		130 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:55111-396-32	1 in 1 CARTON	09/30/2006	
7		170 in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:55111-396-08	1 in 1 CARTON	09/30/2006	
8		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
9	NDC:55111-396-16	5 in 1 CARTON	09/30/2006	
9		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077367	09/30/2006	

Labeler - Dr.Reddys Laboratories Limited (650562841)

Establishment

Name	Address	ID/FEI	Business Operations

Dr.Reddys Laboratories Limited		918608162	analysis(55111-118, 55111-396) , manufacture(55111-118, 55111-396)

Establishment

Name	Address	ID/FEI	Business Operations
Reed Lane Inc		001819879	pack(55111-118, 55111-396)

Establishment

Name	Address	ID/FEI	Business Operations
Dr. Reddy's Laboratories Louisiana LLC		830397282	analysis(55111-118, 55111-396) , manufacture(55111-118, 55111-396)