FAMOTIDINE - famotidine tablet, film coated
CHAIN DRUG MARKETING ASSOCIATION, INC.

Famotidine tablets USP, 10 mg and 20 mg

Active ingredient (in each tablet)

Famotidine USP 10 mg and 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

• adults and children 12 years and over:
• to **relieve**symptoms, swallow 1 tablet with a glass of water. Do not chew.

10 mg:
• 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

20 mg:

• 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° to 25°C (68° to 77°F)
• protect from moisture

Inactive ingredients

10 mg:
carnauba wax, corn starch, hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, sodium starch glycolate, talc, titanium dioxide.

20 mg:

carnauba wax, corn starch, hydroxypropyl cellulose, hypromellose, magnesium

stearate, microcrystalline cellulose, sodium starch glycolate, talc, titanium dioxide, red iron oxide and yellow iron oxide.

Questions or comments?

1-888-375-3784
JUST ONE TABLET prevents and relieves 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

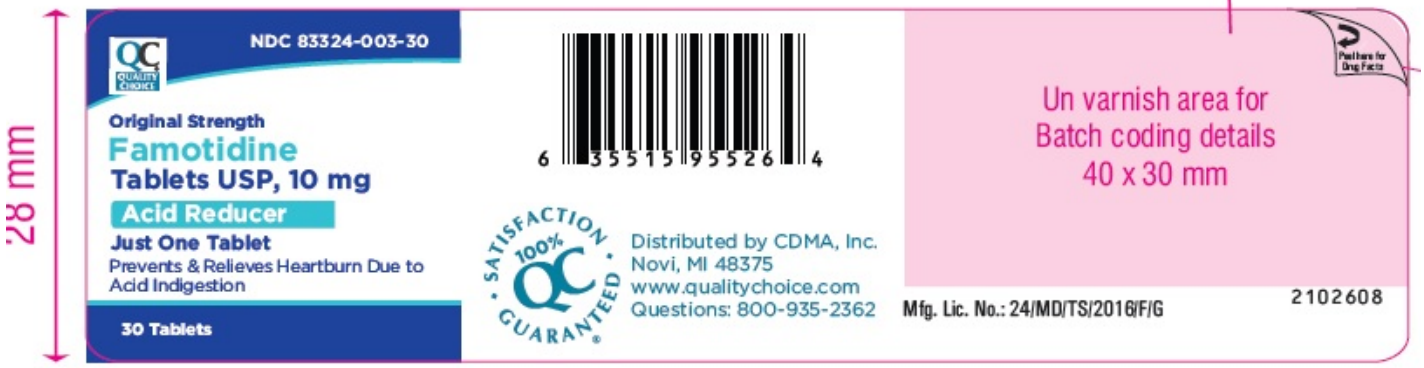
Distributed by CDMA, Inc.
Novi, MI 48375
www.qualitychoice.com
Questions: 800-935-2362

PRINCIPAL DISPLAY PANEL

Famotidine Tablets USP 10 mg - 30s container label

LOT : XXXXXXXXX
Exp : YYYY-MM-DD

Top Layer



28 mm

105 mm

Top Layer Back

28 mm

Active ingredient (in each tablet) ***Purpose***

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

- 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

1

105 mm

Second Layer

28 mm

- 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

- 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

Do not use if foil inner seal imprinted with *"SEALED for YOUR PROTECTION"* is broken or missing.

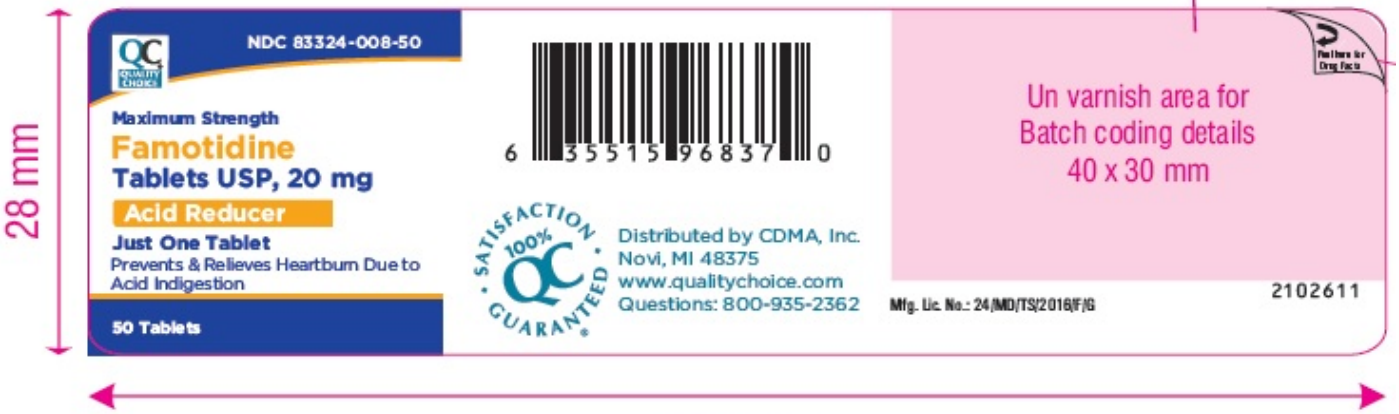
2

Famotidine Tablets USP 10 mg - 30s container carton label

Famotidine Tablets USP 20 mg - 50s container label

LOT : XXXXXXXXX
Exp : YYYY-MM-DD

Top Layer



28 mm

105 mm

Top Layer Back

28 mm

Active ingredient (in each tablet) ***Purpose***

Famotidine USP 20 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

- 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

1

105 mm

Second Layer

28 mm

- 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)

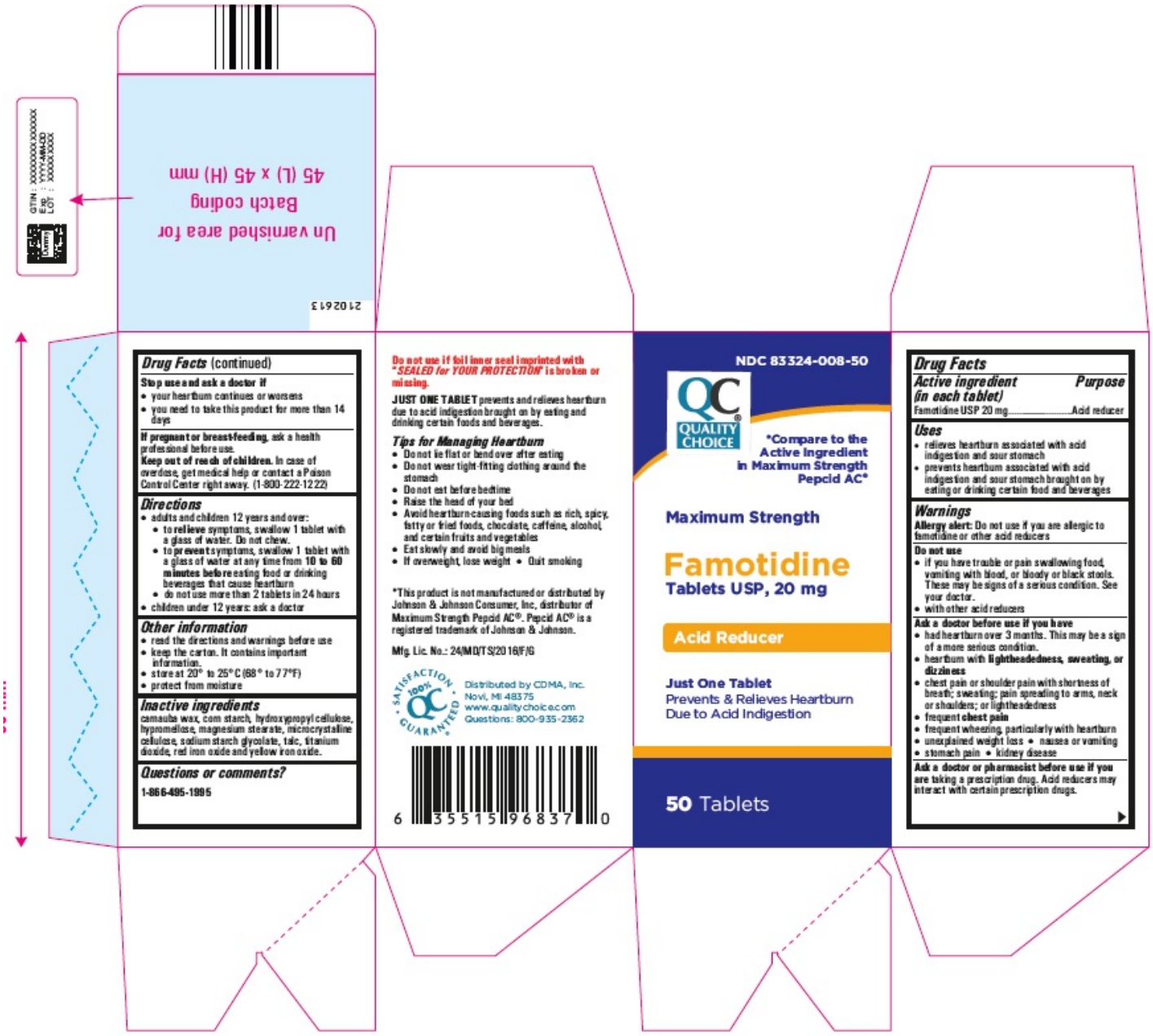
Directions

- 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

Do not use if foil inner seal imprinted with *"SEALED for YOUR PROTECTION"* is broken or missing.

2

Famotidine Tablets USP 20 mg - 50s container carton label



FAMOTIDINE

famotidine tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:83324-003
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)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 36SFW2JZ0W)	
MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	

Product Characteristics

Color	white	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	T;10
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83324-003-30	1 in 1 CARTON	03/06/2024	
1		30 in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA215766	03/06/2024	

FAMOTIDINE

famotidine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:83324-008
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
MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 36SFW2JZ0W)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	yellow (Light yellow)	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	T;11
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83324-008-50	1 in 1 CARTON	03/06/2024	
1		50 in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA215766	03/06/2024	

Labeler - CHAIN DRUG MARKETING ASSOCIATION, INC. (011920774)

Establishment

Name	Address	ID/FEI	Business Operations
Annora Pharma Private Limited		650980746	analysis(83324-003, 83324-008) , manufacture(83324-003, 83324-008)