

FAMOTIDINE - famotidine tablet, film coated
Camber Consumer Care 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

corn starch, hypromellose, magnesium stearate, microcrystalline cellulose, sodium starch glycolate and film coating contains carnauba wax, hydroxypropyl cellulose, hypromellose, talc, titanium dioxide; and additionally 20 mg contains iron oxide red and iron oxide yellow.

Questions or comments?

1-866-495-1995

PRINCIPAL DISPLAY PANEL

Famotidine Tablets USP 10 mg - 30s container label

Top Layer

CAMBER
CONSUMER CARE

NDC 69230-326-30

ORIGINAL STRENGTH
Famotidine Tablets, USP
10 mg
Acid Reducer
Just One Tablet!
Prevents & Relieves Heartburn
Due to Acid Indigestion
30 Tablets

Mfg. Lic. No.: 24(MD)/TS/2016/FIG

5
69230 32630
5

Point here for Drug Facts

Un varnish area for
Batch coding details
40 x 30 mm

Distributed by: Camber Consumer Care, Inc. 2101775
Piscataway, NJ 08854, USA.

Top Layer Back

<i>Active ingredient (in each tablet)</i>	<i>Purpose</i>
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

Second Layer

- 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 10 mg - 10 (1x10) blister carton label



Un varnished area for
Batch coding
45 (L) x 45 (H) mm

2101286

Drug Facts (continued)

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

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

Questions or comments?
1-866-495-1995

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

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

Mfg. Lic. No.: 24/MD/TS/2016/F/G

Distributed by:
Camber Consumer Care, Inc.
Piscataway, NJ 08854, USA.

N
3 69230 32601 5

NDC 69230-326-01

CAMBER
CONSUMER CARE

ORIGINAL STRENGTH
Famotidine
Tablets, USP
10 mg
Acid Reducer

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

100 Tablets

Drug Facts

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 • 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.

Famotidine Tablets USP 20 mg - 30s container label

Top Layer



NDC 69230-327-30

Mfg. Lic. No.: 24/MD/TS/2016/FIG



Un varnish area for
Batch coding details
40 x 30 mm

Distributed by: Camber Consumer Care, Inc. 2101779
Piscataway, NJ 08854, USA.

Top Layer Back

<p>Active ingredient (in each tablet) Purpose Famotidine USP 20 mg..... Acid reducer</p> <p>Uses</p> <ul style="list-style-type: none"> • 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. <p>Warnings Allergy alert: Do not use if you are allergic to famotidine or other acid reducers.</p> <p>Do not use</p> <ul style="list-style-type: none"> • if you have trouble or pain swallowing food, vomiting with blood, or 	<p>bloody or black stools. These may be signs of a serious condition. See your doctor.</p> <ul style="list-style-type: none"> • with other acid reducers. <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> • 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
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Second Layer

<ul style="list-style-type: none"> • nausea or vomiting • stomach pain • kidney disease. <p>Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> • your heartburn continues or worsens • you need to take this product for more than 14 days. <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>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)</p>	<p>Directions</p> <ul style="list-style-type: none"> • adults and children 12 years and over: <ul style="list-style-type: none"> • 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 <p>Do not use if foil inner seal imprinted with "SEALED for YOUR PROTECTION" is broken or missing.</p>
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Famotidine Tablets USP 20 mg - 30s container carton label



Famotidine Tablets USP 20 mg - 10 (1x10) blister carton label



FAMOTIDINE

famotidine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69230-326
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
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: 70097M6130)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 365FW2JZOW)	
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:69230-326-30	1 in 1 CARTON	11/08/2021	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69230-326-60	1 in 1 CARTON	11/08/2021	
2		60 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:69230-326-01	1 in 1 CARTON	11/08/2021	
3		100 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:69230-326-05	1 in 1 CARTON	11/08/2021	
4		500 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:69230-326-10	1 in 1 CARTON	11/08/2021	
5		1000 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	ANDA215766	11/08/2021	

FAMOTIDINE

famotidine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69230-327
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:69230-327-30	1 in 1 CARTON	11/08/2021	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69230-327-50	1 in 1 CARTON	11/08/2021	
2		50 in 1 BOTTLE; Type 0: Not a Combination Product		

3	NDC:69230-327-01	1 in 1 CARTON	11/08/2021	
3		100 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:69230-327-05	1 in 1 CARTON	11/08/2021	
4		500 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:69230-327-10	1 in 1 CARTON	11/08/2021	
5		1000 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	ANDA215766	11/08/2021	

Labeler - Camber Consumer Care Inc (079539968)

Establishment

Name	Address	ID/FEI	Business Operations
Annora Pharma Private Limited		650980746	analysis(69230-326, 69230-327) , manufacture(69230-326, 69230-327)

Revised: 10/2022

Camber Consumer Care Inc