FAMOTIDINE- famotidine tablet
Ascent Pharmaceuticals, Inc.

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

Inactive ingredients

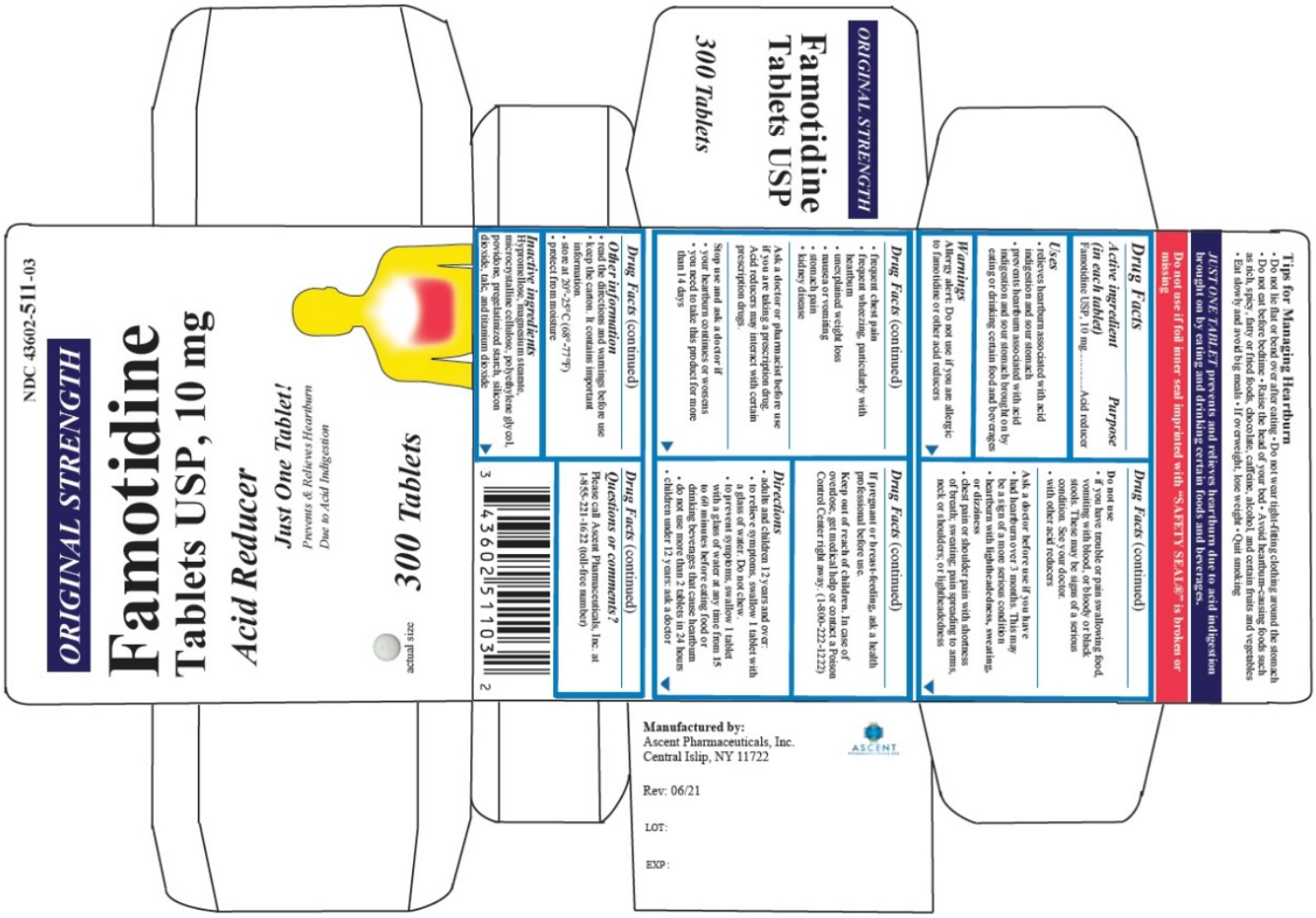
Hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, silicon dioxide, talc, and titanium dioxide

Questions or comments?

Please call Ascent Pharmaceuticals, Inc. at **1-855-221-1622** (toll-free number)

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



NDC 43602-511-03

ORIGINAL STRENGTH

Famotidine

Tablets USP, 10 mg

Acid Reducer

Just One Tablet!

Prevents & Relieves Heartburn Due to Acid Indigestion

300 Tablets

Do not use if foil inner seal imprinted with "SAFETY SEAL®" is broken or missing

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. **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

Inactive ingredients hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, silicon dioxide, talc, and titanium dioxide

Manufactured by:
Ascent Pharmaceuticals, Inc.
Central Islip, NY 11722

Rev: 05/21

LOT:
EXP:

NO VARNISH

NDC 43602-602-03

MAXIMUM STRENGTH

Famotidine

Tablets USP, 20 mg

Acid Reducer

Just One Tablet!

Prevents & Relieves Heartburn Due to Acid Indigestion

actual size

300 Tablets

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 certain foods and beverages.

Do not use if foil inner seal imprinted with "SAFETY SEAL®" is broken or missing

Drug Facts

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 certain food and beverages

Warnings
Allergy alert: Do not use if you are allergic to famotidine or other acid reducers

Drug Facts (continued)

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

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

Drug Facts (continued)

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

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

Drug Facts (continued)
- frequent chest pain
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain
- kidney disease

Famotidine Tablets USP

MAXIMUM STRENGTH

300 Tablets

Manufactured by:
Ascent Pharmaceuticals, Inc.
Central Islip, NY 11722

Rev: 06/21

LOT:
EXP:

Drug Facts (continued)

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
Hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, silicon dioxide, talc, and titanium dioxide

Drug Facts (continued)

Questions or comments?
Please call Ascent Pharmaceuticals, Inc. at 1-855-221-1622 (toll-free number)

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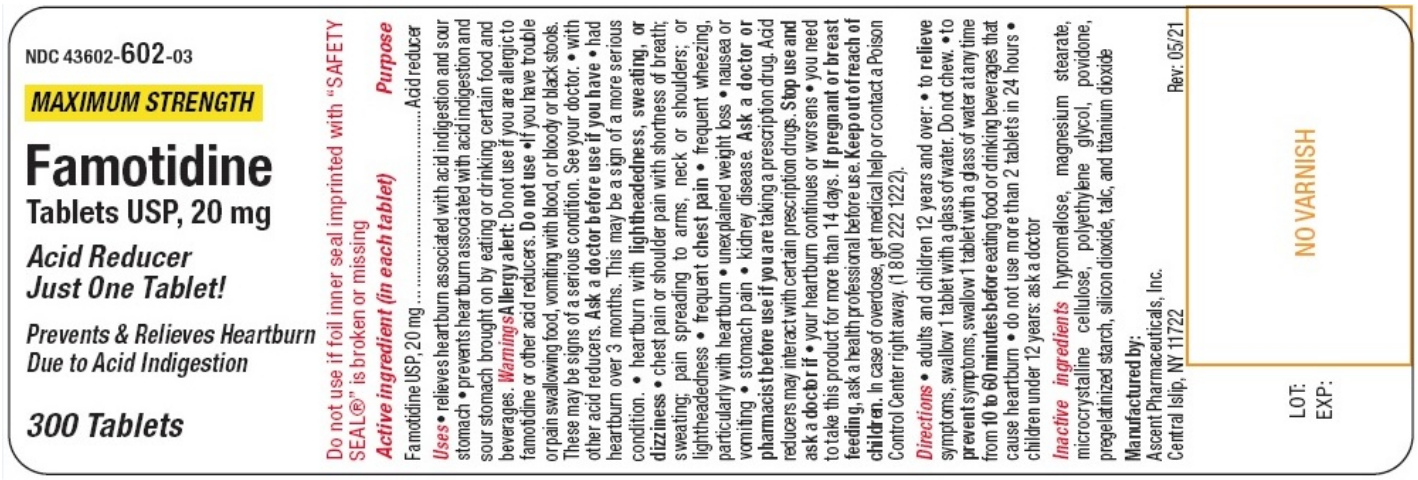

FAMOTIDINE

famotidine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:43602-511
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**
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	white	**Score**	no score
Shape	ROUND	**Size**	5mm
Flavor		**Imprint Code**	T;511
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43602-511-30	1 in 1 CARTON	11/03/2021	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:43602-511-03	1 in 1 CARTON	11/03/2021	
2		300 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	ANDA216030	11/03/2021	

FAMOTIDINE

famotidine tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:43602-602
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
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	T;602

Contains	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43602-602-30	1 in 1 CARTON	11/03/2021	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:43602-602-03	1 in 1 CARTON	11/03/2021	
2		300 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	ANDA216030	11/03/2021	

Labeler - Ascent Pharmaceuticals, Inc. (080938961)

Establishment

Name	Address	ID/FEI	Business Operations
Ascent Pharmaceuticals, Inc.		080938961	manufacture(43602-511, 43602-602) , analysis(43602-511, 43602-602) , pack(43602-511, 43602-602)

Revised: 2/2022 Ascent Pharmaceuticals, Inc.