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

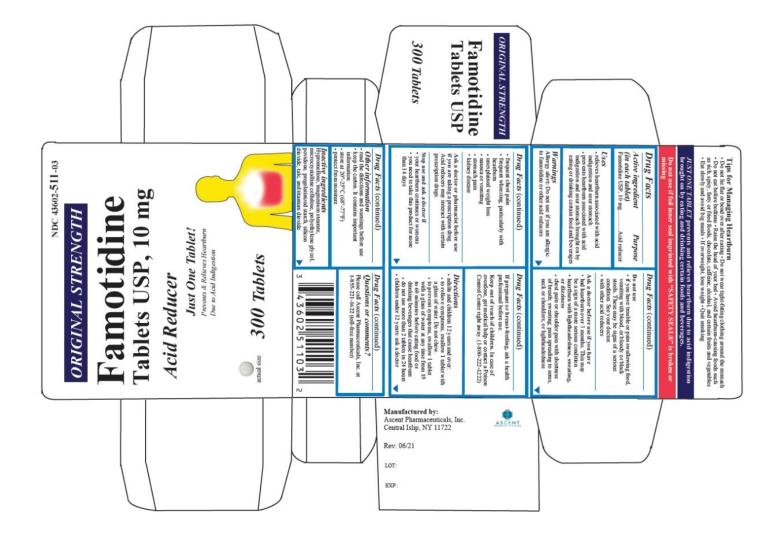
Questions or comments?

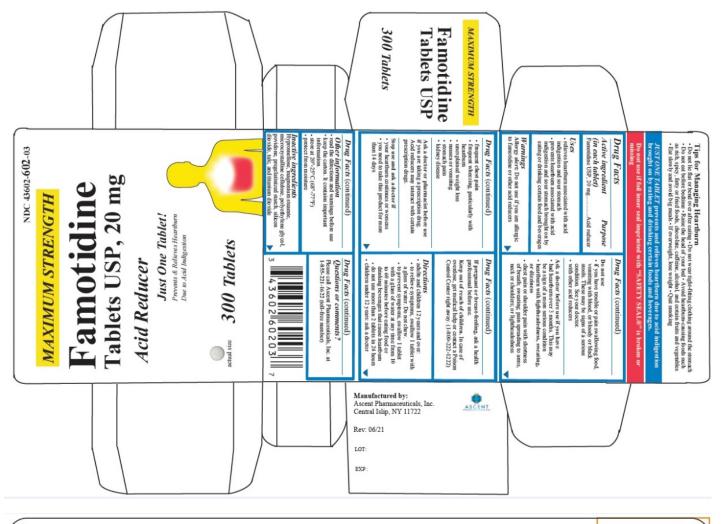
Please call Ascent Pharmaceuticals, Inc. at 1-855-221-1622 (toll-free number)

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





to prevent symptoms, swallow 1 tablet with aglæs of water at any time from 15 to 60 minutes before eating food or drinking beverages that cause hear thurn • do not use more than 2 tablets in 24 hours Purpose beverages. Warmings Allergy alert: Do not use if you are allergic to famotidine or other acid reducers. Do not use off you have trouble had heartburn over 3 months. This may be a sign of a more serious condition. • hear thurn with lightheadedness, sweating, or sweating; pain spreading to arms, neck or shoulders; or Do not use if foil inner seal imprinted with "SAFETY Isses - 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 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 dizziness • chest pain or shoulder pain with shortness of breath; 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 Directions • adults and children 12 years and over: • to relieve symptoms, swallow 1 tablet with a glass of water. Do not chew. Inactive ingredients hypromellose, magnesium stearate, microcrystalline cellulose, potyethylene glycol, povidone, pregelatinized starch, silicon dioxide, talc, and titanium dioxide Rev: 05/21 Acid reducer NDC 43602-511-03 **ORIGINAL STRENGTH** NO VARNISH Famotidine Active ingredient (in each tablet) Control Center right away. (1 800 222 1222) Tablets USP, 10 mg children under 12 years: ask a doctor SEAL®" is broken or missing Acid Reducer Ascent Pharmaceuticals, Inc. Central Islip, NY 11722 Just One Tablet! Famotidine USP, 10 mg .. Prevents & Relieves Heartburn Manufactured by: Due to Acid Indigestion EXP: 300 Tablets

(NDC 43602-602-03	"SAFETY	Addreducer	and sour	ood and llergicto e trouble	ly or black stools. ur doctor. • with vou have • had	a more serious sweating, or tness of breath;	ulders; or wheezing, nausea or	doctor or ndrug. Acid op use and • you need t or breast	a Poison	rt: • to relieve ond chew. • to ater atany time beverages that in 24 hours •	n stearate, povidone, dioxide	Rev: 05/21		
	MAXIMUM STRENGTH	with "S	Acid	digestion	g certain food and if you are allergic to •If you have trouble	or bloody or black stools. See your doctor. • with use if you have • had	of a more serio ss, sweating, ortness of brea	• • •	Ask a doctor or escription drug. Acid drugs. Stop use and worsens ● you need pregnant or breast	epoutor r contact	in bet	magnesium s ne glycol, p and titanium dio	Be	т	
	Famotidine	seal imprinted issing	han	ith acid in	ng or drinking t: Donot use i Do not use •		sign dne th sl	is, neck pain • fre ined weigh	tomach pain • kidney disease. Ask a doctor or before use if you are taking a prescription drug. Aci interact with certain prescription drugs. Stop use and if • your heartburn continues or worsens • you need orduct for more than 1.4 days. If pregnant or breast orduct here the n1.4 days. If pregnant or breast	ical help o 1222).	and children 12 years and over: • to relieve 1 tablet with a glass of water. Do not chew. • to wallow 1 tablet with a glass of water at any time esbefore eating food or drinking beverages that do not use more than 2 tablets in 24 hours • ars: ask a doctor	0	s	VARNISH	
	Tablets USP, 20 mg Acid Reducer	missing	acii tab	ociated w	eating o alert: Do	d, vomiting with blood, of a serious condition. Ask a doctor before	his may t lighthe pulder pa	to arms, t chest pa unexplaine	kidney u are tak tain pres urn conti than 14 (get med 300 222	dren 12 y vith a glas tablet wit eating fo e more tl t doctor			NO VI	
	Just One Tablet!	l inner en or mi	un (m e	tburn ass	ch brought on by eating WarningsAllergy alert: or other acid reducers. D	of a seric Ask a d	over 3 months. Th • heartburn with • chest pain or sh	 frequent frequent neartburn 	stomach pain • before use if you y interact with cert r if • your heartb product for more if	overdose away. (18	Its and childr w1 tablet wit s, swallow1 ta s, swallow1 ta utes before e • do not use years: ask a d	ents hyp cellulose, th, silicon (cals, Inc. 22		
	Prevents & Relieves Heartburn Due to Acid Indigestion	se if foil inn is broken or	P 20	shear	broug	be signs reducers.	er 3 m heartt hest p	pain sp Iness • with hea	tomac before interac if • yo oduct	ase of rright	e adults swallow mptoms, s 60 minute ttburn • o der 12 yei	ingredients alline cellu ted starch, sil	ed by: naceuticals NY 11722		
	300 Tablets	Do not use if SEAL®" is br	Active ingreatent (in each tabled) Famotidine USP 20 mg	Uses • relieves heartburn associated with acid indigestion and sour chome the prevents hear thurn associated with acid indigestion and sour	sour storm ach brought on by eating or drinking certain food and bevrages. <i>Warnings</i> Allergy alert: Donot use if you are allergic famolique or other add reduces. Do not use el'twu tave trouble			2 8	vomiting • stomach pain • kichrey 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 hearthur continues or worsens • you need to take in product for more than 14 days. If pregnant or breast to take the continues or worsens • you need	recurry, as a manuri procession actor user. Report of treater 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 ove symptoms, swallow 1 tablet with a glass of water. De prevent symptoms, swallow 1 tablet with a glass of w prevent symptoms, swallow 1 tablet with a gass of the prevent symptoms, swallow 1 tablet with a gass of the prevent symptom, swallow 1 tablet with a glass of the prevent symptoms, swallow 1 tablet prevent symptoms, swallow 1 tablet with a glass of the prevent symptom symptom and the symptom children under 12 years; ask a doctor	Inactive ingredients hypromello microcrystalline cellulose, polye pregelatinized starch, silicon dioxide,	Manufactured by: Ascent Pharmaceuticals, Inc. Central Islip, NY 11722	LOT: EXP:	

Product Information								
Product Information								
Product Type	HUMAN	OTC DRUG	Item Code (S	ource)	NDC:43	602-511		
Route of Administration	ORAL							
Active Ingredient/Act	ive Moiety	1						
In	gredient N	ame		Basis of Sti	rength	Strength		
FAMOTIDINE (UNII: 5QZ015J	2Z8) (FAMOTIC	INE - UNII:5QZO1	5J2Z8)	FAMOTIDINE		10 mg		
Inactive Ingredients								
-	Ingr	edient Name				Strength		
HYPROMELLOSES (UNII: 3NX	W29V3WO)							
MAGNESIUM STEARATE (UN	II: 70097M6I30)						
MICROCRYSTALLINE CELLU	LOSE (UNII: O	P1R32D61U)						
POLYETHYLENE GLYCOL, U	NSPECIFIED	UNII: 3WJQ0SDW1	A)					
POVIDONE (UNII: FZ 989GH94	E)							
STARCH, CORN (UNII: 08232	NY3SJ)							
SILICON DIOXIDE (UNII: ETJ7	Z6XBU4)							
TALC (UNII: 7SEV7J4R1U)								
TITANIUM DIOXIDE (UNII: 15	FIX9V2JP)							
Product Characterist	ics							
Color white Score no score								
Shape	nape ROUND Size 5mm							
Flavor	Imprint Code T;511							
Contains								

# Item Code	Pac	ckage Description			eting Start Date		eting End Date	
1 NDC:43602-511- 30	1 in 1 CARTON	1	1/03/202	21				
1	30 in 1 BOTTL Product	E; Type 0: Not a Combina	ation					
2 NDC:43602-511- 03	1 in 1 CARTON	l	1	1/03/202	21			
2	300 in 1 BOTT Product	LE; Type 0: Not a Combir	nation					
Marketing	Informat	ion						
Marketing Category		tion Number or Mono Citation	ograph	Mar	keting Start Date	Marl	keting End Date	
ANDA	ANDA21603	0		11/03/	2021			
	E							
FAMOTIDIN								
Product Infor	mation							
Product Type		HUMAN OTC DRUG	ource)	NDC:43602-602				
Route of Admini	stration	ORAL						
Active Ingredi	ent/Active	Mojety						
Active mgreat		dient Name			Basis of Str	onath	Strength	
FAMOTIDINE (UNII:	•				FAMOTIDINE		20 mg	
FAMOTIDINE (UNII: 5QZ015J2Z8) (FAMOTIDINE - UNII:5QZ015J2Z8) FAMOTIDINE 20 mg							J	
Inactive Ingre	dients							
Inactive Ingre	dients	Ingredient Name	9				Strength	
HYPROMELLOSES	(UNII: 3NXW29V	/3WO)	•				Strength	
HYPROMELLOSES MAGNESIUM STEA	(UNII: 3NXW29V RATE (UNII: 70)	/3WO) 097M6I30)	•				Strength	
HYPROMELLOSES MAGNESIUM STEA MICROCRYSTALLIN	(UNII: 3NXW29V NRATE (UNII: 700 NE CELLULOSI	/3WO) 097M6I30) E (UNII: OP1R32D61U)					Strength	
HYPROMELLOSES MAGNESIUM STEA MICROCRYSTALLIN POLYETHYLENE GI	(UNII: 3NXW29V RATE (UNII: 70) NE CELLULOSI LYCOL, UNSPE	/3WO) 097M6I30)					Strength	
HYPROMELLOSES MAGNESIUM STEA MICROCRYSTALLIN POLYETHYLENE GI POVIDONE (UNII: F2	(UNII: 3NXW29V RATE (UNII: 700 NE CELLULOSE LYCOL, UNSPE Z989GH94E)	/3WO) 097M6I30) E (UNII: OP1R32D61U) ECIFIED (UNII: 3WJQ0SDW					Strength	
HYPROMELLOSES MAGNESIUM STEA MICROCRYSTALLIN POLYETHYLENE GI	(UNII: 3NXW29V RATE (UNII: 70) NE CELLULOSI LYCOL, UNSPE Z989GH94E) NII: O8232NY3S	/3WO) 097M6I30) E (UNII: OP1R32D61U) ECIFIED (UNII: 3WJQ0SDW					Strength	
HYPROMELLOSES MAGNESIUM STEA MICROCRYSTALLIN POLYETHYLENE GI POVIDONE (UNII: FZ STARCH, CORN (UN	(UNII: 3NXW29V RATE (UNII: 70) NE CELLULOSE LYCOL, UNSPE Z989GH94E) NII: 08232NY35 (UNII: ETJ7Z6XB	/3WO) 097M6I30) E (UNII: OP1R32D61U) ECIFIED (UNII: 3WJQ0SDW					Strength	
HYPROMELLOSES MAGNESIUM STEA MICROCRYSTALLIN POLYETHYLENE GI POVIDONE (UNII: FZ STARCH, CORN (UN SILICON DIOXIDE ((UNII: 3NXW29V RATE (UNII: 70) NE CELLULOSE LYCOL, UNSPE Z989GH94E) NII: 08232NY3S (UNII: ETJ7Z6XB 4R1U)	/3WO) 097M6I30) E (UNII: OP1R32D61U) ECIFIED (UNII: 3WJQ0SDW J) 5U4)					Strength	
HYPROMELLOSES MAGNESIUM STEA MICROCRYSTALLIN POLYETHYLENE GI POVIDONE (UNII: F2 STARCH, CORN (UM SILICON DIOXIDE (TALC (UNII: 7SEV7)4	(UNII: 3NXW29V RATE (UNII: 70) NE CELLULOSI LYCOL, UNSPE Z989GH94E) NII: 08232NY3S (UNII: 08232NY3S (UNII: ETJ7Z6XB 4R1U) E (UNII: 15FIX9V	/3WO) 097M6I30) E (UNII: OP1R32D61U) ECIFIED (UNII: 3WJQ0SDW J) 5U4)					Strength	
HYPROMELLOSES MAGNESIUM STEA MICROCRYSTALLIN POLYETHYLENE GI POVIDONE (UNII: FZ STARCH, CORN (UN SILICON DIOXIDE (TALC (UNII: 75EV7)4 TITANIUM DIOXIDE	(UNII: 3NXW29V RATE (UNII: 70) NE CELLULOSI LYCOL, UNSPE Z989GH94E) NII: 08232NY3S (UNII: 08232NY3S (UNII: ETJ7Z6XB 4R1U) E (UNII: 15FIX9V	/3WO) 097M6I30) E (UNII: OP1R32D61U) ECIFIED (UNII: 3WJQ0SDW J) 3U4) /2JP)				no score	Strength	
HYPROMELLOSES MAGNESIUM STEA MICROCRYSTALLIN POLYETHYLENE GI POVIDONE (UNII: FZ STARCH, CORN (UN SILICON DIOXIDE (TALC (UNII: 75EV7)4 TITANIUM DIOXIDE	(UNII: 3NXW29V RATE (UNII: 700 NE CELLULOSE LYCOL, UNSPE Z989GH94E) NII: 08232NY3S (UNII: 08232NY3S (UNII: 08232NY3S (UNII: 08232NY3S (UNII: 08232NY3S (UNII: 08232NY3S (UNII: 08232NY3S (UNII: 08232NY3S (UNII: 08232NY3S (UNII: 08232NY3S) (UNII: 08232NY3S) (UNII: 08232NY3S) (UNII: 08232NY3S) (UNII: 08232NY3S) (UNII: 15FIX9V	(3WO) 097M6I30) E (UNII: OP1R32D61U) ECIFIED (UNII: 3WJQ0SDW J) 3U4) (2JP) te Score					Strength	

Co	ontains									
Packaging										
#	ltem 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						
AN	DA	ANDA216030	11/03/2021							

Labeler - Ascent Pharmaceuticals, Inc. (080938961)

Establishment

Name	Address	,	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.