

FAMOTIDINE- famotidine tablet, film coated
Graviti Pharmaceuticals Private Limited

Famotidine Tablets, USP 10 mg and 20 mg

ACTIVE INGREDIENT (IN EACH TABLET)

Original Strength

Drug Facts

Famotidine 10 mg

Maximum Strength

Drug Facts

Famotidine 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 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 a medical help or contact a Poison Control Center right away. (1-800-222-1222)

DIRECTIONS

Directions for 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

Directions for 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

FDA approved dissolution test specifications differ from USP.

INACTIVE INGREDIENT

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

For 10 mg: iron oxide black and iron oxide red,

For 20 mg: iron oxide yellow and iron oxide red.

QUESTIONS OR COMMENTS?

Call toll-free weekdays 9 AM to 5 PM EST at **1-855-298-4506**

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Principal Display Panel - 10 mg Tablet: Container Label

NDC 69844-097-01

Original Strength

*Compare to the active ingredient in Pepcid AC®

Famotidine Tablet, USP 10 mg

Acid Reducer

Just One Tablet!

Prevent & Relives Heartburn Due to Acid Indigestion

30 Tablets

Marketed by Graviti Pharmaceuticals Inc.

Made in India.

Marketed by:
 Graviti Pharmaceuticals Inc.,
 Wilmington, Delaware-19801,
 USA.
 Made in India

*This product is not
 manufactured or distributed
 by Johnson & Johnson
 Consumer Inc., distributor of
 Original Strength Pepcid AC®.
 Pepcid AC® is a registered
 trademark of Johnson &
 Johnson.

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.



Lot:
 Exp Date:

Drug Facts

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



Drug Facts (continued)

■ 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



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
 ■ FDA approved dissolution test specifications differ from USP

Inactive Ingredients Carnauba wax, Corn starch, Hydroxypropyl cellulose, Hydroxypropyl methyl cellulose, Iron oxide black, Iron oxide red, Magnesium stearate, Microcrystalline cellulose, Sodium starch glycolate, Talc and Titanium dioxide.

Questions or comments?

Call toll-free weekdays 9 AM to 5 PM EST at 1-855-298-4506

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 food, chocolate, caffeine, alcohol, and certain fruits and vegetables ■ Eat slowly and avoid big meals ■ If overweight, lose weight
 ■ Quit smoking

Principal Display Panel - 10 mg Tablet: Carton Label

NDC 69844-097-01

Original Strength

*Compare to the active ingredient in Pepcid AC®

Famotidine Tablet, USP 10 mg

Acid Reducer

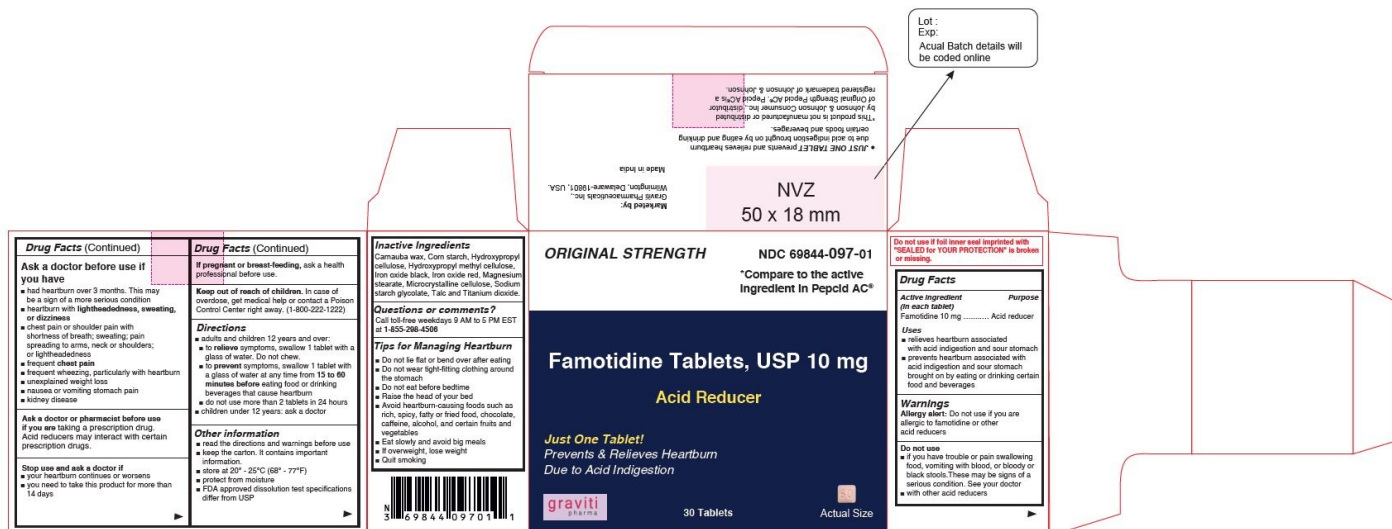
Just One Tablet!

Prevent & Relives Heartburn Due to Acid Indigestion

30's Tablets Bottles pack

Marketed by Graviti Pharmaceuticals Inc.

Made in India.



Principal Display Panel - 10 mg Tablet: Carton Label

NDC 69844-097-04

Original Strength

*Compare to the active ingredient in Pepcid AC®

Famotidine Tablet, USP 10 mg

Acid Reducer

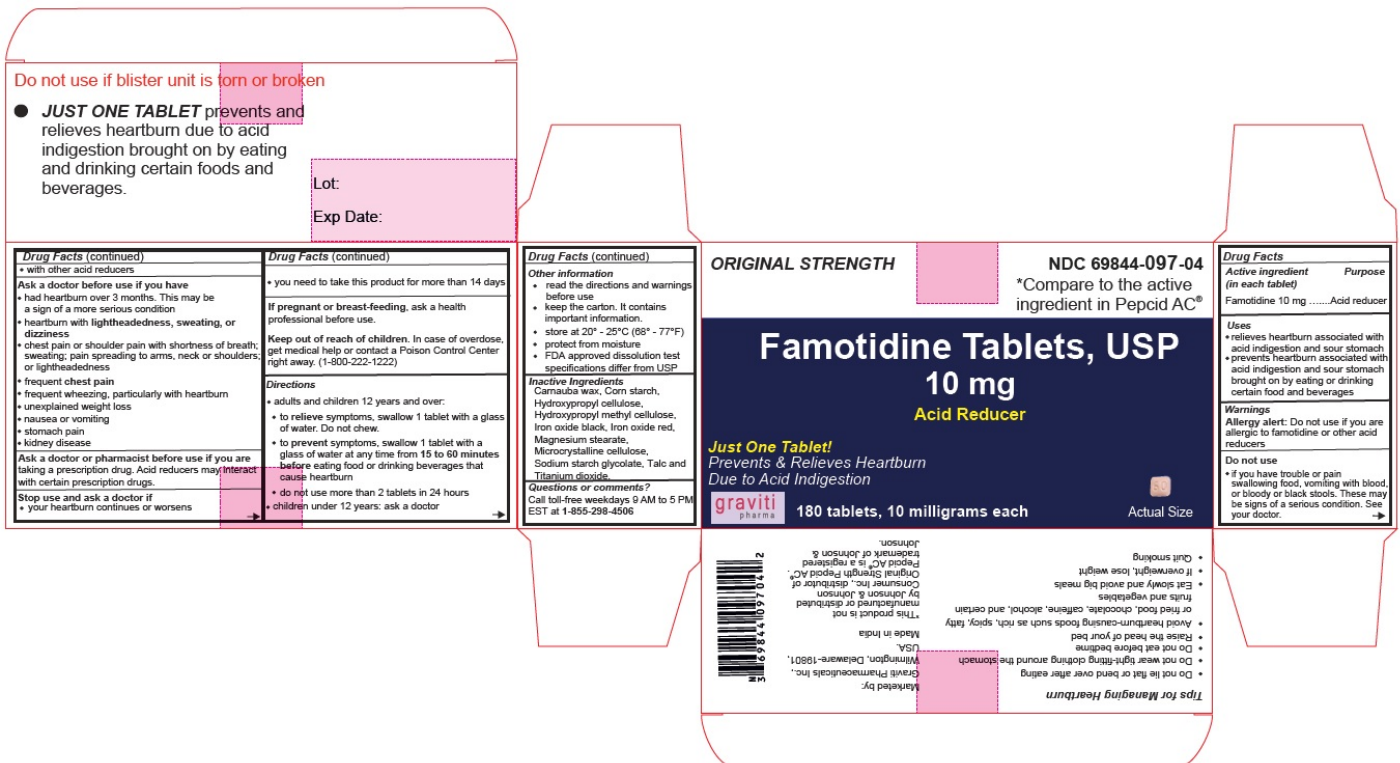
Just One Tablet!

Prevent & Relives Heartburn Due to Acid Indigestion

10's Blister Pack

Marketed by Graviti Pharmaceuticals Inc.

Made in India.



Principal Display Panel - 20 mg Tablets: Container Label

NDC 69844-098-01

Maximum Strength

*Compare to the active ingredient in Pepcid AC®

Famotidine Tablet, USP 20 mg

Acid Reducer

Just One Tablet!

Prevent & Relives Heartburn Due to Acid Indigestion

30 Tablets

Marketed by Graviti Pharmaceuticals Inc.

Made in India.

Marketed by:
Graviti Pharmaceuticals Inc.,
Wilmington, Delaware-19801,
USA.
Made in India

*This product is not
manufactured or distributed by
Johnson & Johnson Consumer
Inc., distributor of Maximum
Strength Pepcid AC®.Pepcid AC®
is a registered trademark of
Johnson & Johnson.

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



- 1 Tablet relieves heartburn due to acid indigestion.
- Famotidine Tablets USP prevents heartburn due to acid indigestion brought on by eating and drinking certain foods and beverages



Lot:

Exp Date:

Drug Facts

Active ingredient (in each tablet)	Purpose
Famotidine 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



Drug Facts (continued)

■ 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 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)

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

■ FDA approved dissolution test specifications differ from USP

Inactive Ingredients Carnauba wax, Corn starch, Hydroxypropyl cellulose, Hydroxypropyl methyl cellulose, Iron oxide yellow, Iron oxide red, Magnesium stearate, Microcrystalline cellulose, Sodium starch glycolate, Talc and Titanium dioxide.

Questions or comments?

Call toll-free weekdays 9 AM to 5 PM EST at 1-855-298-4506

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 food, chocolate, caffeine, alcohol, and certain fruits and vegetables ■ Eat slowly and avoid big meals ■ If overweight, lose weight
■ Quit smoking

Principal Display Panel - 20 mg Tablets: Carton Label

NDC 69844-098-01

Maximum Strength

*Compare to the active ingredient in Pepcid AC®

Famotidine Tablet, USP 20 mg

Acid Reducer

Just One Tablet!

Prevent & Relives Heartburn Due to Acid Indigestion

30's Tablets Bottle Pack

Marketed by Graviti Pharmaceuticals Inc.

Made in India.



Principal Display Panel - 20 mg Tablets: Carton Label

NDC 69844-098-04

Maximum Strength

*Compare to the active ingredient in Pepcid AC®

Famotidine Tablet, USP 20 mg

Acid Reducer

Just One Tablet!

Prevent & Relives Heartburn Due to Acid Indigestion

10's Blister Pack

Marketed by Graviti Pharmaceuticals Inc.

Made in India.

Do not use if blister unit is torn or broken

- 1 Tablet relieves heartburn due to acid indigestion.
- Famotidine Tablets, USP prevents heartburn due to acid indigestion brought on by eating and drinking certain foods and beverages

Lot: _____
Exp Date: _____

<p>Drug Facts (continued)</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 wheezing, particularly with heartburn unexplained weight loss 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 	<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> 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>Drug Facts (continued)</p> <p>Other information</p> <ul style="list-style-type: none"> 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 FDA approved dissolution test specifications differ from USP <p>Inactive Ingredients</p> <p>Carnauba wax, Corn starch, Hydroxypropyl cellulose, Iron oxide yellow, Iron oxide red, Magnesium stearate, Microcrystalline cellulose, Sodium starch glycolate, Talc and Titanium dioxide</p> <p>Questions or comments?</p> <p>Call toll-free weekdays 9 AM to 5 PM EST at 1-855-298-4506</p>	<p>MAXIMUM STRENGTH</p> <p>NDC 69844-098-04 *Compare to the active ingredient in Pepcid AC®</p> <p>Famotidine Tablets, USP 20 mg Acid Reducer</p> <p>Just One Tablet! Prevents & Relieves Heartburn Due to Acid Indigestion</p> <p>graviti pharma 200 tablets, 20 milligrams each Actual Size</p>	<p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active ingredient (in each tablet)</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Famotidine 20 mg</td> <td>Acid reducer</td> </tr> </tbody> </table> <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</p> <p>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 bloody or black stools. These may be signs of a serious condition. See your doctor. 	Active ingredient (in each tablet)	Purpose	Famotidine 20 mg	Acid reducer
Active ingredient (in each tablet)	Purpose							
Famotidine 20 mg	Acid reducer							

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 food, chocolate, caffeine, alcohol, and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking

Marketed by: Graviti Pharmaceuticals Inc., Wilmington, Delaware-19801, USA
This product is not manufactured or distributed by Johnson & Johnson
Consumer Strength Pepcid AC® is a registered trademark of Johnson & Johnson

FAMOTIDINE			
famotidine tablet, film coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69844-097
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
	STARCH, CORN (UNII: O8232NY3SJ)		
	HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)		
	MAGNESIUM STEARATE (UNII: 70097M6130)		
	MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK)		
	MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)		
	SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0S QX4D)		
	HYPROMELLOSE 2910 (15 MPA.S) (UNII: 365FW2JZ0W)		

HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ 8H6N6OH)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

TALC (UNII: 7SEV7J4R1U)

CARNAUBA WAX (UNII: R12CBM0EIZ)

FERRIC OXIDE RED (UNII: 1K09F3G675)

FERROSOFERRIC OXIDE (UNII: XM0M87F357)

Product Characteristics

Color	PINK (Light pink to pink)	Score	no score
Shape	ROUND (rounded square biconvex)	Size	5mm
Flavor		Imprint Code	60
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69844-097-01	1 in 1 CARTON	03/14/2024	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69844-097-02	1 in 1 CARTON	03/14/2024	
2		100 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:69844-097-04	18 in 1 CARTON	03/14/2024	
3		10 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	ANDA218461	03/14/2024	

FAMOTIDINE

famotidine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69844-098
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
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE 101 (UNII: 7T9FYH5QMK)	
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 365FW2JZ0W)	
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 (rounded square biconvex)	Size	5mm
Flavor		Imprint Code	35
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69844-098-01	1 in 1 CARTON	03/14/2024	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69844-098-02	1 in 1 CARTON	03/14/2024	
2		100 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:69844-098-04	20 in 1 CARTON	03/14/2024	
3		10 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	ANDA218461	03/14/2024	

Labeler - Graviti Pharmaceuticals Private Limited (650884781)

Registrant - Graviti Pharmaceuticals Private Limited (650884781)

Establishment

Name	Address	ID/FEI	Business Operations
Graviti Pharmaceuticals Private Limited		650884781	MANUFACTURE(69844-097, 69844-098) , ANALYSIS(69844-097, 69844-098)

Revised: 10/2024

Graviti Pharmaceuticals Private Limited