FAMOTIDINE- famotidine tablet, film coated HEB

Drug Facts

ACTIVE INGREDIENT (IN EACH TABLET)

Famotidine, USP 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

- with other acid reducers
- if you have kidney disease, except under the advice and supervision of a doctor
- 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.

Ask a doctor before use if you have

- frequent **chest pain**
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain
- 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

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

OTHER INFORMATION

- store at 20° to 25°C (68° to 77°F)
- protect from moisture
- read the directions and warnings before use
- keep the carton. It contains important information.

INACTIVE INGREDIENTS

Colloidal silicon dioxide, hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol 400, pregelatinized starch, talc, titanium dioxide

QUESTIONS?

Call 1-800-406-7984

PATIENT INFORMATION

- JUST ONE TABLET prevents and relieves heartburn due to acid indigestion brought on by eating and drinking certain foods and beverages.
- TAMPER EVIDENT: DO NOT USE IF THE CARTON OR PRINTED FOIL UNDER CAP IS OPEN OR TORN.

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

PRINCIPAL DISPLAY PANEL - 20 mg Tablet Bottle Carton

Compare to Maximum Strength Pepcid AC^{\circledast} active ingredient[†]

NDC 37808-036-50

H-E-B $_{\mathbb{R}}$

Maximum Strength
Acid Controller
Famotidine Tablets, USP 20 mg

Acid Reducer

Just One Tablet Prevents & Relieves Heartburn Due to Acid Indigestion

actual size

50 TABLETS



- keep the cartor, it contains important information.
 - protect from moisture
 read the directions and warnings before use

 - store at 20° to 25° C (68° to 77° F)

Other information

Drug Facts (continued)

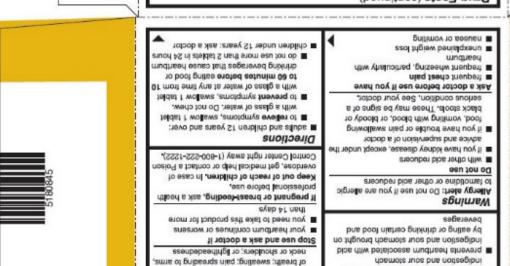
■ relieves heartburn associated with acid

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Famolidine, USP 20 mg

Active ingredient

(in each tablet)



chest pain or shoulder pain with shortness

sweating, or dizziness

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nearthum with lightheadedness,

a sign of a more serious condition.

had heartburn over 3 months. This may be



FAMOTIDINE

famotidine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-036
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Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FAMO TIDINE (UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8)	FAMOTIDINE	20 mg

Inactive Ingredients

inactive ingredients	
Ingredient Name	Strength
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
HYDROXYPROPYL CELLULOSE (1200000 MW) (UNII: RFW2ET671P)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)

- 10 000 0101 000 10 000				
Color	white	Score	no score	
Shape	ROUND	Size	8 m m	
Flavor		Imprint Code	036	
Contains				

Packaging

	0 0			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-036-26	1 in 1 CARTON	04/09/2014	
1		25 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:37808-036-50	1 in 1 CARTON	04/09/2014	
2	1	50 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing	Infor	mation
TITUL INC CITIES	TIII VI	u tiv ii

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

ANDA	ANDA090283	04/09/2014	

Labeler - HEB (007924756)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment			
Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(37808-036)

Revised: 12/2018 HEB