

**SIGNATURE CARE ACID CONTROLLER MAXIMUM STRENGTH- famotidine tablet,
film coated
Praxis, LLC**

Better Living Brands LLC Acid Controller Drug Facts

Active ingredient (in each tablet)

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 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

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

carnauba wax, colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide

Questions or comments?

1-800-719-9260

Principal Display Panel

COMPARE TO Maximum Strength Pepcid[®] AC active ingredient

Quality Guaranteed

Maximum Strength

Acid Controller

FAMOTIDINE TABLETS, 20 mg

Acid Reducer

Just one tablet prevents & relieves heartburn due to acid indigestion

Actual Size


SEE NEW WARNINGS

50 TABLETS



19471 LU C2

CODE AREA



Maximum Strength

Acid Controller

FAMOTIDINE TABLETS, 20 mg
Acid Reducer


DO NOT USE IF PRINTED FOIL UNDER CAP IS BROKEN OR MISSING

3 2130 72549 7

S 1872

RD 20071

Scan here for more information



Drug Facts	Drug Facts (continued)
<p>Active ingredient (in each tablet) Famotidine 20 mg.....Acid reducer</p> <p>Purpose 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</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. ■ 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. 	<ul style="list-style-type: none"> ■ 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 <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>

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

Drug Facts (continued)

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Drug Facts (continued)

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Inactive ingredients carnauba wax, colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide

Questions or comments? 1-800-719-9260

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

SIGNATURE CARE ACID CONTROLLER MAXIMUM STRENGTH

famotidine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59368-281
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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	

MAGNESIUM STEARATE (UNII: 70097M6I30)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)		
TALC (UNII: 7SEV7J4R1U)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		

Product Characteristics			
Color	white	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	L194
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59368-281-02	1 in 1 CARTON	09/04/2015	
1		50 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:59368-281-01	1 in 1 CARTON	09/04/2015	
2		200 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	ANDA077351	09/04/2015	

Labeler - Praxis, LLC (016329513)

Establishment			
Name	Address	ID/FEI	Business Operations
Praxis, LLC		016329513	manufacture(59368-281) , label(59368-281) , pack(59368-281)