

# **EQUALINE HEARTBURN PREVENTION- famotidine tablet, film coated**

## **Praxis, LLC**

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### **SuperValu Inc. Heartburn Prevention 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, and titanium dioxide

**Questions or comments?**

**1-855-423-2630**

**Principal Display Panel**

EQUALINE<sup>®</sup>

compare to Maximum Strength Pepcid<sup>®</sup> AC active ingredient

maximum strength

heartburn prevention

famotidine tablets, 20mg (acid reducer)

just one tablet prevents & relieves heartburn due to acid indigestion

SEE NEW WARNINGS

25 tablets

actual size

**DO NOT USE IF PRINTED BLISTER UNIT IS BROKEN OR TORN**

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

**EQUALINE®**

compare to  
Maximum Strength  
Pepcid®AC  
active ingredient\*  
NDC 41163-001-02

maximum strength  
**heartburn  
prevention**  
famotidine tablets, 20mg  
(acid reducer)

*just one tablet  
prevents & relieves heartburn  
due to acid indigestion*

**SEE NEW WARNINGS**

**25 tablets**



actual size

OPEN OTHER END

**Drug Facts**

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(in each tablet)

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**Drug Facts (continued)**

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

**Drug Facts (continued)**

**Questions or comments?** 1-855-42-3630

GLUTEN FREE

**EQUALINE®**

maximum strength

**heartburn prevention**

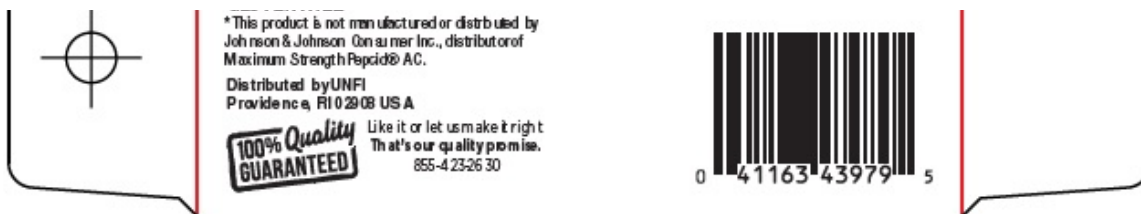
famotidine tablets, 20mg • (acid reducer)

CONVENIENT RECLOSING TAB



10447 EL C3

19447 EL C3



## EQUALINE HEARTBURN PREVENTION

famotidine tablet, film coated

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59368-290
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:59368-290-01	1 in 1 CARTON	12/17/2014	
1		50 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	12/05/2014	

**Labeler -** Praxis, LLC (016329513)

## Establishment

Name	Address	ID/FEI	Business Operations
Praxis, LLC		016329513	label(59368-290) , pack(59368-290) , manufacture(59368-290)

Revised: 1/2023

Praxis, LLC