MAXIMUM STRENGTH- famotidine tablet, film coated
Praxis, LLC

Publix Super Markets, Inc. Maximum Strength 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 68°-77°F (20°-25°C)
- 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

Principal Display Panel

maximum strength

FAMOTIDINE TABLETS, 20 mg

ACID REDUCER

ACTUAL SIZE

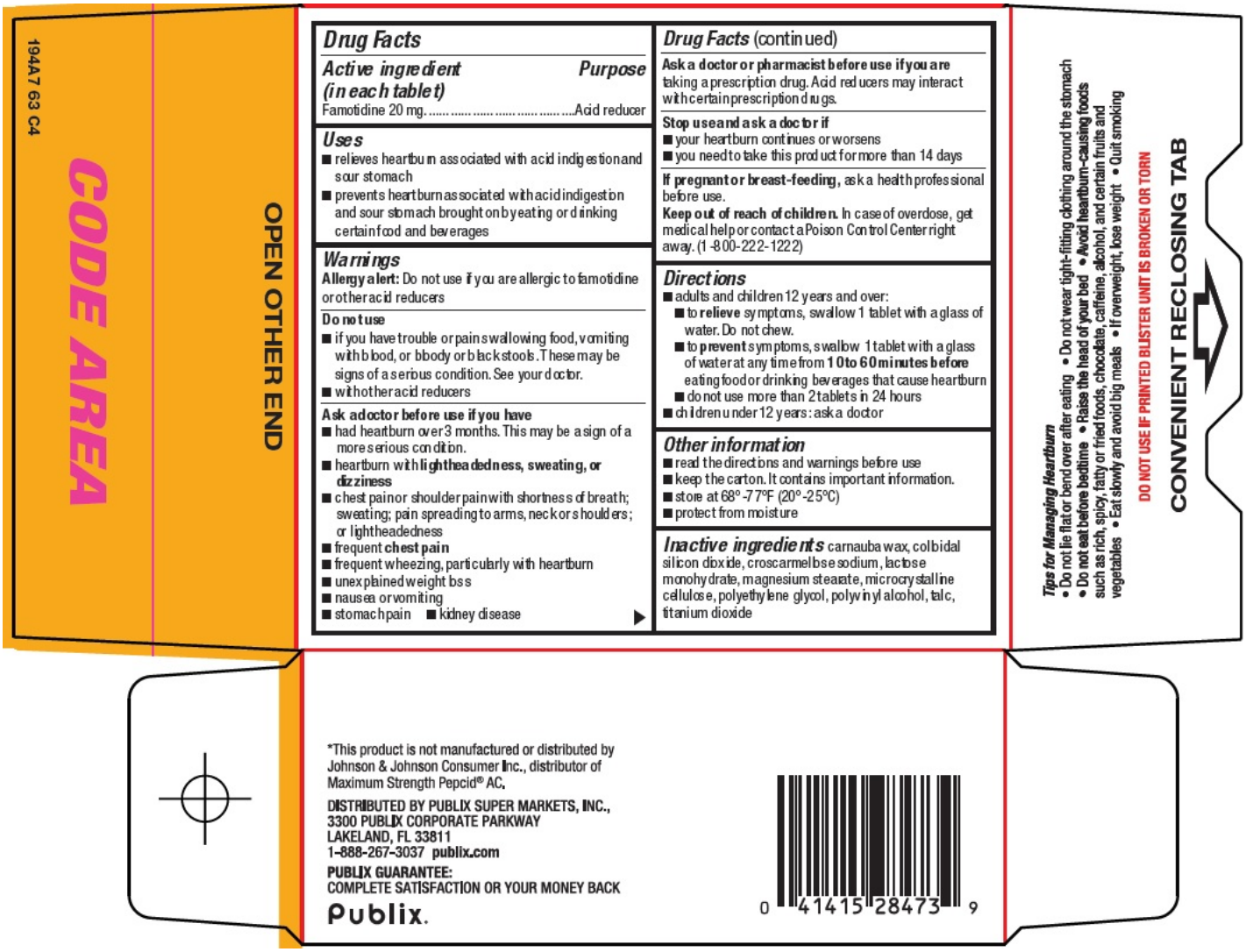
Just one tablet prevents & relieves heartburn due to acid indigestion

25 TABLETS

SEE NEW WARNINGS

Compare to Maximum Strength Pepcid ®AC active ingredient


maximumstrength
FAMOTIDINE TABLETS, 20 mg
ACID REDUCER
JUST ONE TABLET prevents and relieves heartburn due to acid indigestion brought on by eating and drinking certain foods and beverages.
NDC 56062-194-02
maximumstrength
FAMOTIDINE TABLETS, 20 mg
ACID REDUCER
ACTUAL SIZE
• Just one tablet prevents & relieves heartburn due to acid indigestion
25 TABLETS
Compare to Maximum Strength Pepcid® AC active ingredient*
SEE NEW WARNINGS



MAXIMUM STRENGTH

famotidine tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59368-291
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)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	

LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
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:59368-291-01	1 in 1 CARTON	12/07/2007	
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	12/03/2007	

Labeler - Praxis, LLC (016329513)

Establishment

Name	Address	ID/FEI	Business Operations
Praxis, LLC		016329513	manufacture(59368-291) , label(59368-291) , pack(59368-291)

Revised: 1/2023 Praxis, LLC