## TOPCARE ACID REDUCER- famotidine tablet, film coated Topco Associates LLC

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#### Topco Associates LLC. Acid Reducer 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

colloidal silicon dioxide, croscarmellose sodium, FD&C blue #1 aluminum lake, hypromellose, lactose (monohydrate), magnesium stearate, maltodextrin, microcrystalline cellulose, modified food starch, natural and artificial flavor, sucralose, titanium dioxide, triacetin

#### **Questions or comments?**

1-888-423-0139

#### Package/Label Principal Display Panel

TopCare<sub>®</sub> health

COMPARE TO MAXIMUM STRENGTH PEPCID® AC ACTIVE INGREDIENT

MAXIMUM STRENGTH

Acid Reducer

FAMOTIDINE TABLETS, 20 mg

#### **ACID REDUCER**

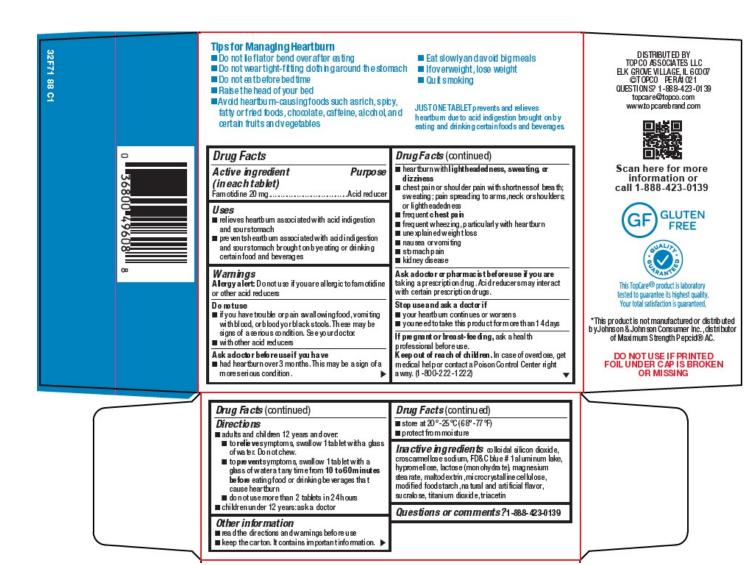
Releases a cooling sensation in mouth & throat

Just One Tablet Prevents & Relieves Heartburn Due to Acid Indigestion actual size

50 TABLETS

**COOL MINT FLAVOR** 





#### TOPCARE ACID REDUCER

famotidine tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76162-300
Route of Administration	ORAL		

# Active Ingredient/Active Moiety Ingredient Name Basis of Strength FAMOTIDINE (UNII: 5QZ015J2Z8) (FAMOTIDINE - UNII:5QZ015J2Z8) FAMOTIDINE 20 mg

Inactive Ingredients		
Ingredient Name	Strength	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		

LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics			
Color	BLUE	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	32F
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:76162-300- 71	1 in 1 CARTON	09/25/2022		
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	09/25/2022	

### Labeler - Topco Associates LLC (006935977)

Revised: 10/2022 Topco Associates LLC