RUGBY FAMOTIDINE- famotidine tablet, film coated Rugby Laboratories

Rugby Laboratories Famotidine 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?

1-800-645-2158

Principal Display Panel

Compare to the active ingredient of Maximum Strength Pepcid® AC

Maximum Strength

Famotidine Tablets

20 mg

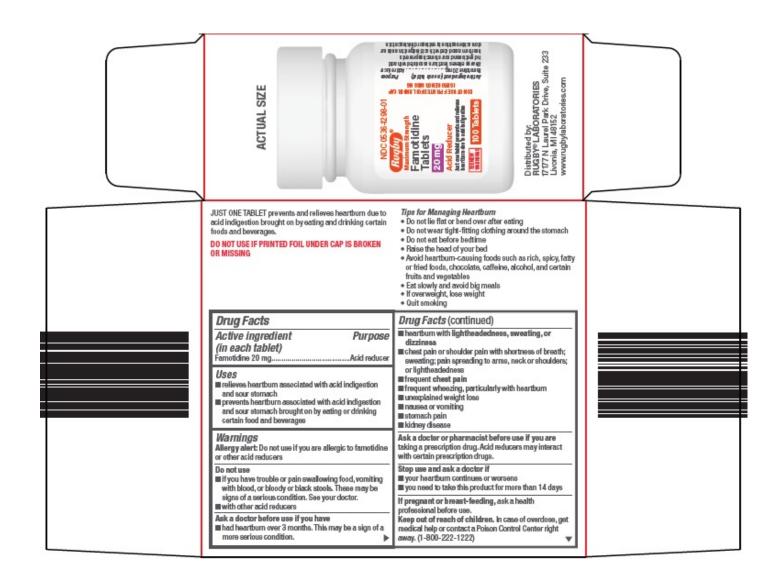
Acid Reducer

Actual Size

Just one tablet prevents and relieves heartburn due to acid indigestion SEE NEW WARNINGS

100 Tablets





RUGBY FAMOTIDINE

famotidine tablet, film coated

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:0536-1298 Route of Administration ORAL

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

Inactive Ingredients			
Ingredient Name	Strength		
CARNAUBA WAX (UNII: R12CBM0EIZ)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)			
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					

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:0536-1298- 01	1 in 1 CARTON	09/14/2020			
1		100 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	09/14/2020		

Labeler - Rugby Laboratories (079246066)

Revised: 7/2021 Rugby Laboratories