ORIGINAL STRENGTH HEARTBURN PREVENTION- famotidine tablet KROGER COMPANY

719R_Kroger_41226-719_Famotidine Tablets USP 10 mg

Drug Facts

Active ingredient (in each tablet)

Famotidine USP 10 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

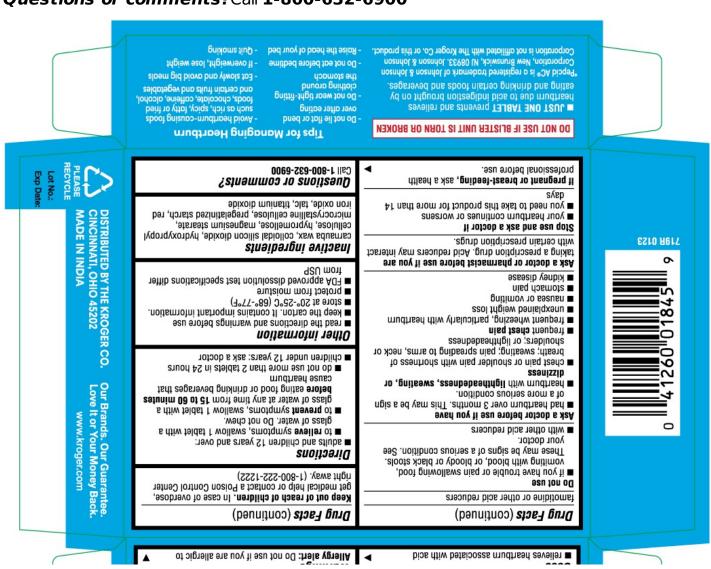
- adults and children 12 years and over:
- -to **relieve** symptoms, swallow 1 tablet with a glass of water. Do not chew.
- -to **prevent** symptoms, swallow 1 tablet with a glass of water at any time from **15 to 60 minutes before** eating food or drinking beverages that cause heartburn
- -do not use 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
- FDA approved dissolution test specifications differ from USP

Inactive ingredients carnauba wax, colloidal silicon dioxide, hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, pregelatinized starch, red iron oxide, talc, titanium dioxide

Questions or comments? Call 1-800-632-6900





ORIGINAL STRENGTH HEARTBURN PREVENTION

famotidine tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41226-719

Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
FAMOTIDINE (UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8)	FAMOTIDINE	10 mg	

Inactive Ingredients			
Ingredient Name	Strength		
FERRIC OXIDE RED (UNII: 1K09F3G675)			
TALC (UNII: 7SEV7J4R1U)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)			

CARNAUBA WAX (UNII: R12CBM0EIZ)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: 08232NY3SJ)	

Product Characteristics			
Color	pink	Score	no score
Shape	SQUARE	Size	7mm
Flavor		Imprint Code	86
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41226- 719-06	3 in 1 CARTON	05/05/2023	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA217543	05/05/2023	

Labeler - KROGER COMPANY (006999528)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment				
Name	Address	ID/FEI	Business Operations	
MARKSANS PHARMA LIMITED		925822975	manufacture(41226-719)	

Revised: 5/2023 KROGER COMPANY