HEARTBURN RELIEF ORIGINAL STRENGTH- famotidine tablet
Proficient Rx LP

Major Pharmaceuticals Heartburn Relief Drug Facts

Active ingredient (in each tablet)

Famotidine 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

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.

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 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 and light

Inactive ingredients

carnauba wax, hypromellose, iron oxide red, iron oxide yellow, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, pregelatinized starch, talc, titanium dioxide, triacetin

Questions or comments?

1-800-719-9260

Principal Display Panel

Original Strength

Heartburn Relief

Famotidine Tablets, 10 mg Acid Reducer

Just One Tablet

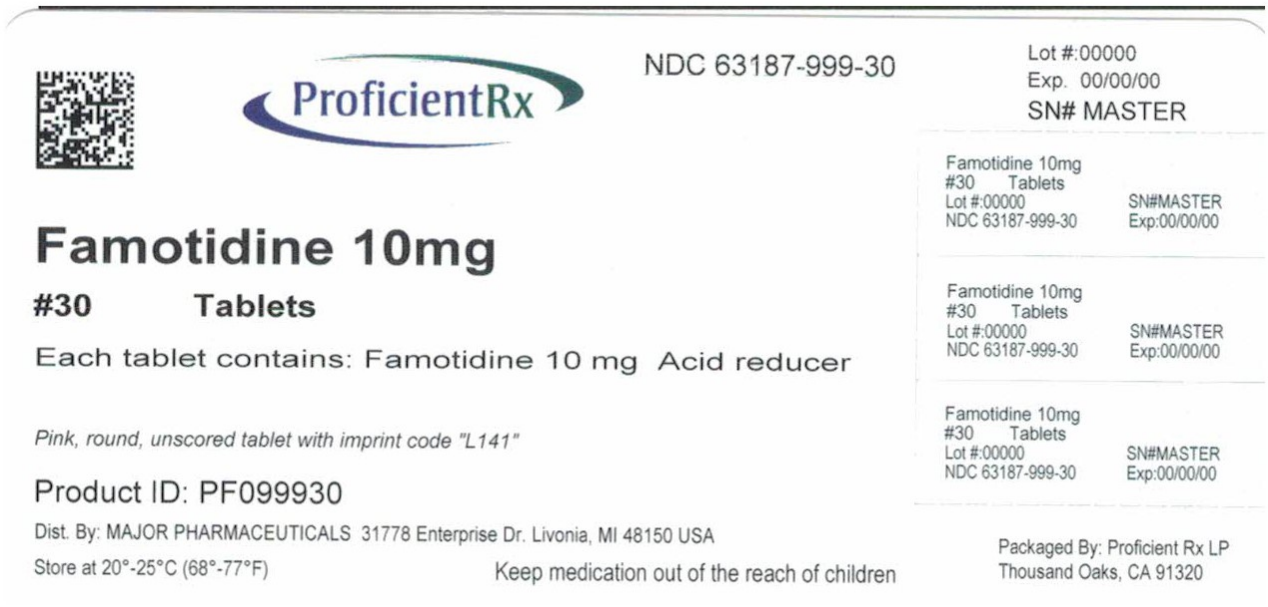
Prevents & Relieves Heartburn due to Acid Indigestion

COMPARE TO the active ingredient of ORIGINAL STRENGTH PEPCID® AC

ACTUAL SIZE

30 Tablets

TABLETS



HEARTBURN RELIEF ORIGINAL STRENGTH

famotidine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63187-999(NDC:0904-5529)
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**
CARNAUBA WAX (UNII: R12CBM0EIZ)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	PINK	**Score**	no score
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	L141
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63187-999-10	10 in 1 BOTTLE; Type 0: Not a Combination Product	04/02/2018	
2	NDC:63187-999-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/02/2018	
3	NDC:63187-999-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	04/02/2018	
4	NDC:63187-999-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/02/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075400	09/09/2009	

Labeler - Proficient Rx LP (079196022)

Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	REPACK(63187-999) , RELABEL(63187-999)

Revised: 10/2019 Proficient Rx LP