

FAMOTIDINE- famotidine tablet, film coated, extended release
SPIRIT PHARMACEUTICALS,LLC

HEARTBURN RELIEF

Drug Facts

Active ingredient (in each tablet)

Famotidine USP 10mg

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

- store at 25°-30°C (77°-86°F).
- read the directions and warnings before use
- protect from moisture.
- keep the carton and package insert. They contain important information.

Inactive ingredients

hydroxypropyl cellulose, hypromellose, iron oxide red, magnesium stearate, microcrystalline cellulose, polyethylene glycol 400, pregelatinized starch, talc, titanium dioxide

Questions or comments?

1-800-xxx-xxxx

Distributed By: Greenbrier International, Inc.
Chesapeake, VA 23320

PRINCIPAL DISPLAY PANEL - 12 Tablet Blister Pack Carton

ASSURED™

**Compare to the
active ingredient
in Pepcid® AC***

**Original Strength
HEARTBURN
RELIEF**

FAMOTIDINE TABLETS USP, 10 mg

ACID REDUCER

**Just One Tablet Relieves &
Prevents Heartburn Due to
Acid Indigestion**

12 TABLETS (12 DOSES)

Drug Facts (continued)

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 ■ stomach pain ■ frequent wheezing, particularly with heartburn ■ unexplained weight loss ■ nausea or vomiting
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
 ■ store at 25°-30°C (77°-86°F). ■ read the directions and warnings before use
 ■ protect from moisture. ■ keep the carton and package insert. They contain important information.

Inactive ingredients hydroxypropyl cellulose, hypromellose, iron oxide red, magnesium stearate, microcrystalline cellulose, polyethylene glycol 400, pregelatinized starch, talc, titanium dioxide

Questions or comments? 1-800-XXX-XXXX

Drug Facts

Active ingredient (in each tablet) Famotidine USP 10mg

Purpose Acid reducer ▲

Compare to the active ingredient in Pepcid® AC



Original Strength

HEARTBURN RELIEF

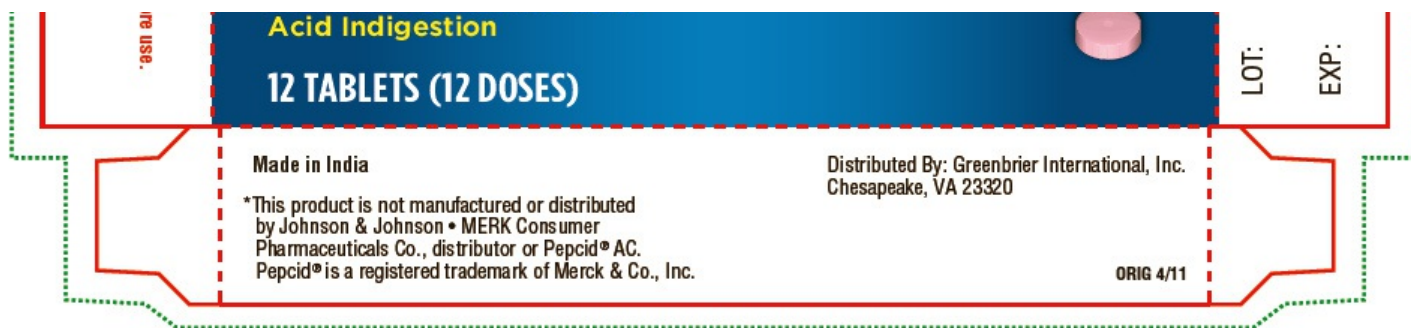
FAMOTIDINE TABLETS USP, 10 mg

ACID REDUCER

Just One Tablet Relieves & Prevents Heartburn Due to



DO NOT USE IF THE INDIVIDUAL BUSTER UNIT IS OPEN OR TORN.
IMPORTANT: Read the directions, consumer information leaflet and warnings before use. Keep the carton. It contains important information.



FAMOTIDINE

famotidine tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-0007
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
HYDROXYPROPYL CELLULOSE (TYPE H) (UNII: RFW2ET671P)	
TALC (UNII: 7SEV7J4R1U)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
WATER (UNII: 059QF0KO0R)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	PINK	Score	no score
Shape	OVAL	Size	8mm
Flavor		Imprint Code	W972
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-0007-0	2 in 1 CARTON		
1		6 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077146	08/19/2013	

Labeler - SPIRIT PHARMACEUTICALS,LLC (179621011)

Revised: 8/2013

SPIRIT PHARMACEUTICALS,LLC