

FAMOTIDINE- famotidine tablet, film coated
TWIN MED LLC

Famotidine Tablet, Film Coated

Drug Facts

Active ingredient (in each tablet)

Famotidine USP, 10 mg and 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 (of 10 mg) with a glass of water at any time from **15 to 60 minutes before** eating food or drinking beverages that cause heartburn
 - to **prevent** symptoms, swallow 1 tablet (of 20 mg) 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
- compares to the active ingredient in Zantac 360

Inactive ingredients

Microcrystalline Cellulose, Pre-gelatinized Starch, Sodium Starch glycolate, Hydroxypropyl Cellulose, Magnesium stearate, Hypromellose, Titanium dioxide, Triacetin, Talc, Macrogol

Questions or comments?

Questions ? call toll-free 1-844-912-4012

**Distributed by:
ProCure Products
Santa Fe Springs, CA 90670**

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Famotidine 10 mg

PROCURE
PRODUCTS

Compare to the active ingredient in Original Strength PEPICID® AC*

Original Strength
FAMOTIDINE
10 mg TABLETS Acid Reducer

Prevents & Relieves Heartburn Due to Acid Indigestion

300 COUNT

PCOTC122
NDC 55681-341-03

DO NOT USE IF PRINTED SEAL UNDER CAP IS MISSING OR DAMAGED

Drug Facts

Active Ingredient (in each tablet) Famotidine, USP 10 mg.....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 foods and beverages

Warnings

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- 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 light-headedness, sweating or dizziness
- chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness
- heartburn with frequent chest pain
- heartburn with 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

PEEL FOR DIRECTIONS

LIFT HERE

8 1651640172417

Famotidine 20 mg

PROCURE
PRODUCTS

Compare to the active ingredient in Maximum Strength PEPICID® AC*

Maximum Strength
FAMOTIDINE
20 mg TABLETS Acid Reducer

Prevents & Relieves Heartburn Due to Acid Indigestion

300 COUNT

PCOTC123
NDC 55681-342-03

DO NOT USE IF PRINTED SEAL UNDER CAP IS MISSING OR DAMAGED

Drug Facts

Active Ingredient (in each tablet) Famotidine, USP 20 mg.....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 foods 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.

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- stomach pain
- kidney disease

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Stop use and ask a doctor if your heartburn continues or worsens

PEEL FOR DIRECTIONS

LIFT HERE

8 1651640172514

FAMOTIDINE

famotidine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55681-342
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FAMOTIDINE (UNII: 5QZ015J2Z8) (FAMOTIDINE - UNII:5QZ015J2Z8)	FAMOTIDINE	20 mg

Inactive Ingredients

Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
HYDROXYPROPYL CELLULOSE (110000 WAMW) (UNII: 5Y0974F5PW)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	white (white to off-white)	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	V;15
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55681-342-03	300 in 1 BOTTLE; Type 0: Not a Combination Product	09/07/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA215822	01/28/2022	

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Ingredient Name	Strength
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Labeler - TWIN MED LLC (009579330)

Revised: 3/2023

TWIN MED LLC