

**FAMOTIDINE- famotidine tablet, film coated
LEADER/ Cardinal Health 110, Inc.**

5688-Leader

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.

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

- side effects occur. You may report side effects to FDA at 1-800-FDA-1088.
- 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
- store at 20°-25°C (68°-77°F)
- protect from moisture
- meets USP Dissolution Test 2

colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, sodium starch glycolate, talc, titanium dioxide.

Questions or comments?

1-800-231-4670:
weekdays 9am-5pm EST

DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43017
www.myleader.com 1-800-200-6313

*This product is not manufactured or distributed by Kenvue Inc., owner of the registered trademark Pepcid AC®.

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

NDC 70000-0710-1

Maximum Strength

Acid Reducer

Famotidine Tablets USP, 20 mg

Just One Tablet Prevents
& Relieves Heartburn Due
to Acid Indigestion

COMPARE TO MAXIMUM STRENGTH PEPCID AC® active ingredient*

200
TABLETS



FAMOTIDINE

famotidine tablet, film coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70000-0710 |
| 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 |
|---|----------|
| POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) | |

| | |
|--|--|
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| TALC (UNII: 7SEV7J4R1U) | |
| SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|----------|
| Color | white | Score | no score |
| Shape | ROUND | Size | 6mm |
| Flavor | | Imprint Code | C;29 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:70000-0710-1 | 1 in 1 CARTON | 12/04/2024 | |
| 1 | | 200 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 | ANDA218003 | 12/04/2024 | |

Labeler - LEADER/ Cardinal Health 110, Inc. (063997360)

Revised: 2/2025

LEADER/ Cardinal Health 110, Inc.