TOPCARE ACID REDUCER- famotidine tablet, film coated Praxis, LLC

Topco Associates LLC. Acid Reducer Drug Facts

Active ingredient (in each tablet)

Famotidine 20 mg

Purpose

Acid reducer

Uses

- 1. relieves heartburn associated with acid indigestion and sour stomach
- 2. 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

- 1. your heartburn continues or worsens
- 2. 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

- 1. adults and children 12 years and over:
- 2. to **relieve**symptoms, swallow 1 tablet with a glass of water. Do not chew.
- 3. to **prevent**symptoms, swallow 1 tablet with a glass of water at any time from **10 to 60 minutesbefore**eating food or drinking beverages that cause heartburn
- 4. do not use more than 2 tablets in 24 hours
- 5. children under 12 years: ask a doctor

Other information

- 1. read the directions and warnings before use
- 2. keep the carton. It contains important information.
- 3. store at 20°-25°C (68°-77°F)
- 4. protect from moisture

Inactive ingredients

carnauba wax, colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide

Questions or comments?

1-888-423-0139

Principal Display Panel

TopCare Rhealth

COMPARE TO MAXIMUM STRENGTH PEPCID ® AC ACTIVE INGREDIENT

MAXIMUM STRENGTH

Acid Reducer

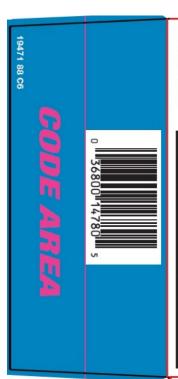
FAMOTIDINE TABLETS, 20 mg

ACID REDUCER

Just One Tablet

Prevents & Relieves Heartburn Due to Acid Indigestion





DO NOT USE IF PRINTED FOIL UNDER CAP IS BROKEN OR MISSING

Tips for Managing Heartburn

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the
- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol, and certain fruits and vegetables
- Eat slowly and avoid big meals If overweight, lose weight Quit smoking

JUST ONE TABLET prevents and relieves heartburn due to acid indigestion brought on by eating and drinking certain foods and beverages

Drug Facts

Active ingredient (in each tablet) amotidine 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 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.

Drug Facts (continued)

- 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)

DISTRIBUTED BY TOPCO ASSOCIATES LLC ELK GROVE VILLAGE, IL 60007 ©TOPCO PERA0521 QUESTIONS? 1-888-423-0139 topcare@topco.com www.topcarebrand.com



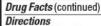
Scan here for more information or call 1-888-423-0139



This TonCare® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

*This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of Maximum Strength Pepcid® AC.





- 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 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. ▶
- protect from moisture

Drug Facts (continued) store at 20°-25°C (68°-77°F)

Inactive ingredients carnauba wax, colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc titanium dioxide

Questions or comments? 1-888-423-0139



TOPCARE ACID REDUCER

famotidine tablet, film coated

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:59368-273

Route of Administration ORAL

Active Ingredient/Active Moiety

Basis of Strength Ingredient Name Strength FAMOTIDINE (UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8) **FAMOTIDINE** 20 mg

Inactive Ingredients

| Ingredient Name | Strength | |
|------------------------------------------|----------|--|
| CARNAUBA WAX (UNII: R12CBM0EIZ) | | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | | |
| CROSCARMELLOSE SODIUM (UNII: M280L1HH48) | | |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | | |

| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
|-----------------------------------------------------|--|
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

| Product Characteristics | | | |
|-------------------------|-------|--------------|----------|
| Color | white | Score | no score |
| Shape | ROUND | Size | 8mm |
| Flavor | | Imprint Code | L194 |
| Contains | | | |

| P | Packaging | | | | |
|---|----------------------|----------------------------------------------------|-------------------------|-----------------------|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:59368-273- 02 | 1 in 1 CARTON | 10/16/2006 | | |
| 1 | | 50 in 1 BOTTLE; Type 0: Not a Combination Product | | | |
| 2 | NDC:59368-273- 01 | 1 in 1 CARTON | 02/02/2021 | | |
| 2 | | 100 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 | ANDA077351 | 09/28/2006 | |
| | | | |

Labeler - Praxis, LLC (016329513)

| Establishment | | | | |
|---------------|---------|-----------|-------------------------------------------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Praxis, LLC | | 016329513 | manufacture(59368-273) , label(59368-273) , pack(59368-273) | |

Revised: 1/2023 Praxis, LLC