

LEADER ACID REDUCER COMPLETE- famotidine, calcium carbonate, magnesium hydroxide tablet, chewable
Cardinal Health

Cardinal Health Acid Reducer Complete Drug Facts

Active ingredients (in each chewable tablet)

Famotidine 10 mg

Calcium carbonate 800 mg

Magnesium hydroxide 165 mg

Purposes

Acid reducer

Antacid

Use

relieves heartburn associated with acid indigestion and sour stomach

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. Antacids 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:
- **do not swallow tablet whole: chew completely**
- to relieve symptoms, **chew** 1 tablet before swallowing
- do not use more than 2 chewable tablets in 24 hours
- children under 12 years: ask a doctor

Other information

- **each tablet contains:** calcium 330 mg; magnesium 80 mg
- Phenylketonurics: Contains Phenylalanine 2 mg per tablet
- read the directions and warnings before use
- read the bottle label. It contains important information.
- store at 20-25°C (68-77°F)
- protect from moisture

Inactive ingredients

anhydrous lactose, aspartame, dextrates, ferric oxide, glyceryl monostearate, lactose monohydrate, magnesium stearate, microcrystalline cellulose, natural peppermint flavor, polyacrylate dispersion, polysorbate 80, povidone, pregelatinized starch, sodium starch glycolate, talc

Questions or comments?

1-800-719-9260

Principal Display Panel

Dual Action

Acid Reducer Complete

Famotidine, 10 mg | Calcium Carbonate, 800 mg

Magnesium Hydroxide, 165 mg | Tablets (Chewable)

Acid Reducer + Antacid

Cool Mint Favor

Just One Tablet Relieves Heartburn Due to Acid Indigestion

COMPARE TO PEPCID COMPLETE® active ingredients

25 CHEWABLE TABLETS

Actual Size

100% Money Back Guarantee

SEE NEW WARNINGS

LEADER²⁵
Dual Action Acid Reducer Complete
 Famotidine, 10 mg | Calcium Carbonate, 800 mg
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 Acid Reducer + Antacid

Cool Mint Flavor
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25 CHEWABLE TABLETS
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COMPARE TO PEPICID COMPLETE
 active ingredients
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TIP for Managing Heartburn

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach
- 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

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

Drug Facts (continued)

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 acid reflux.

Ask a doctor ■ before use if you have ■ bad heartburn over 3 months. This may be a more serious condition. ■ chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arm, neck, or shoulder; or lightheadedness. ■ frequent chest pain ■ frequent vomiting, particularly with heartburn ■ frequent indigestion ■ trouble swallowing ■ trouble breathing ■ stomach pain ■ kidney disease

Ask a doctor or pharmacist ■ before use if you are taking a prescription drug. Antacids and acid reducers may interact with other prescription drugs.

Stop use and ask a doctor if ■ your heartburn continues or worsens ■ you need to take the product for more than 14 days

Keep out of reach of children. In case of Poison Control Center, please call (1-800-222-1222)

Directions ■ Adults and children 12 years and older: Chew 1 tablet before swallowing. Do not use more than 25 chewable tablets in 24 hours unless under 12 years; ask a doctor.

Other information ■ Each tablet contains calcium 330 mg, magnesium 80 mg ■ Phenylephrine: Contains Phenylephrine 2 mg per tablet ■ Each three-pouch and contains immediate information. ■ Store at 20°-25°C (68°-77°F) ■ protect from moisture

100% Money Back Guarantee
 Return to date of purchase for a satisfied return.

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| LEADER ACID REDUCER COMPLETE | | | |
|--------------------------------------------------------------------------------------------------------------|----------------|---------------------|----------------|
| famotidine, calcium carbonate, magnesium hydroxide tablet, chewable | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70000-0416 |
| Route of Administration | ORAL | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| FAMOTIDINE (UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8) | | FAMOTIDINE | 10 mg |
| CALCIUM CARBONATE (UNII: H0G9379FGK) (CARBONATE ION - UNII:7UJQ5OPE7D, CALCIUM CATION - UNII:2M83C4R6ZB) | | CALCIUM CARBONATE | 800 mg |
| MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838, HYDROXIDE ION - UNII:9159UV381P) | | MAGNESIUM HYDROXIDE | 165 mg |
| Inactive Ingredients | | | |
| Ingredient Name | | Strength | |
| ANHYDROUS LACTOSE (UNII: 3S Y5LH9 PMK) | | | |
| ASPARTAME (UNII: Z0H242BBR1) | | | |
| DEXTRATES (UNII: G263MI44RU) | | | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | | | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | | | |

| | |
|-----------------------------------------------|--|
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) | |
| TALC (UNII: 7SEV7J4R1U) | |

Product Characteristics

| | | | |
|-----------------|------------------------------------|---------------------|----------|
| Color | ORANGE (PEACH WITH WHITE SPECKLES) | Score | no score |
| Shape | ROUND | Size | 18mm |
| Flavor | MINT | Imprint Code | L546 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------------------------------------|----------------------|--------------------|
| 1 | NDC:70000-0416-1 | 25 in 1 BOTTLE; Type 0: Not a Combination Product | 09/28/2018 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| ANDA | ANDA077355 | 09/28/2018 | |

Labeler - Cardinal Health (097537435)

Revised: 4/2020

Cardinal Health