# PEPCID COMPLETE- famotidine, calcium carbonate, and magnesium hydroxide tablet, chewable Kenvue Brands LLC

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# **Pepcid Complete**

# **Drug Facts**

| Active ingredients (in each chewable tablet) | Purposes     |
|--|--------------|
| Famotidine 10 mg                             | Acid reducer |
| Calcium carbonate 800 mg                     | Antacid      |
| Magnesium hydroxide 165 mg                   | 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 and 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:
  - 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 320 mg, magnesium 70 mg
- read the directions and warnings before use
- read the bottle. It contains important information.
- store at 20°-25°C (68°-77°F)
- protect from moisture
- do not use if foil inner seal imprinted with "Sealed For Your Safety" is broken or missing

# **Inactive ingredients**

cellulose acetate, corn starch, crospovidone, dextrose excipient, FD&C blue no. 1 aluminum lake, flavors, gum arabic, hydroxypropyl cellulose, hypromellose, lactose monohydrate, magnesium stearate, maltodextrin, mineral oil, sucralose, yellow iron oxide

# **Questions or comments?**

call **1-800-755-4008** (toll-free) or **215-273-8755** (collect)

#### PRINCIPAL DISPLAY PANEL

NDC 16837-891-66

**DUAL ACTION** 

Pepcid ®

Complete

Famotidine 10 mg-Acid reducer

Calcium carbonate 800 mg-Antacid

Magnesium hydroxide 165 mg-Antacid

Just One Tablet!

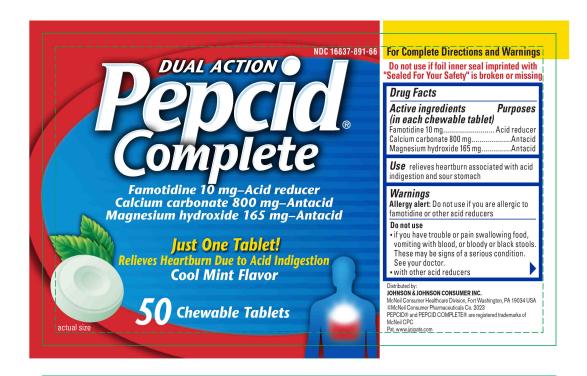
Relieves Heartburn Due to Acid Indigestion

Cool Mint Flavor

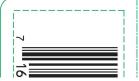
50

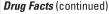
Chewable Tablets

actual size



#### Drug Facts (continued) 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 kidnev disease Ask a doctor or pharmacist before use if you are taking a prescription drug. Antacids and 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:





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Acid Reducer + Antacid Famotidine 10 mg per tablet Calcium carbonate 800 mg per tablet Magnesium hydroxide 165 mg per tablet



Shown actual size

**50 Chewable Tablets** Distributed by: JOHNSON & JOHNSON CONSUMER INC.

McNeil Consumer Healthcare Division, Fort Washington, PA 19034 USA 
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Pat. www.jjcipats.com

#### Tips 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

# **PEPCID COMPLETE**

famotidine, calcium carbonate, and magnesium hydroxide tablet, chewable

| Product Information     |                |                    |               |  |
|-------------------------|----------------|--------------------|---------------|--|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:16837-891 |  |
| Route of Administration | ORAL           |                    |               |  |

| Active Ingredient/Active Moiety  |                          |          |  |
|--|--------------------------|----------|--|
| Ingredient Name  | <b>Basis of Strength</b> | Strength |  |
| FAMOTIDINE (UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8)             | FAMOTIDINE               | 10 mg    |  |
| CALCIUM CARBONATE (UNII: H0G9379FGK) (CARBONATE ION - UNII: 7UJQ50PE7D)  | CALCIUM CARBONATE        | 800 mg   |  |
| MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S) (HYDROXIDE ION - UNII:9159UV381P) | MAGNESIUM<br>HYDROXIDE   | 165 mg   |  |

| Inactive Ingredients                                    |          |  |
|---|----------|--|
| Ingredient Name   | Strength |  |
| CELLULOSE ACETATE (UNII: 3J2P07GVB6)                    |          |  |
| STARCH, CORN (UNII: O8232NY3SJ)                         |          |  |
| CROSPOVIDONE (UNII: 2S7830E561)                         |          |  |
| FERRIC OXIDE YELLOW (UNII: EX43802MRT)                  |          |  |
| DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)           |          |  |
| FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)        |          |  |
| <b>ACACIA</b> (UNII: 5C5403N26O)                        |          |  |
| HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH) |          |  |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)            |          |  |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)                  |          |  |
| MAGNESIUM STEARATE (UNII: 70097M6I30)                   |          |  |
| MALTODEXTRIN (UNII: 7CVR7L4A2D)                         |          |  |
| MINERAL OIL (UNII: T5L8T28FGP)                          |          |  |
| SUCRALOSE (UNII: 96K6UQ3ZD4)                            |          |  |
|   |          |  |

| Product Characteristics |       |              |          |
|-------------------------|-------|--------------|----------|
| Color                   | green | Score        | no score |
| Shape                   | ROUND | Size         | 18mm     |
| Flavor                  | MINT  | Imprint Code | P        |
| Contains                |       |              |          |

| P | Packaging            |   |                         |                       |  |
|---|----------------------|---|-------------------------|-----------------------|--|
| # | Item Code            | Package Description                               | Marketing Start<br>Date | Marketing End<br>Date |  |
| 1 | NDC:16837-891-<br>25 | 25 in 1 BOTTLE; Type 0: Not a Combination Product | 03/01/2009              |                       |  |
| 2 | NDC:16837-891-<br>50 | 50 in 1 BOTTLE; Type 0: Not a Combination Product | 03/01/2009              |                       |  |
| 3 | NDC:16837-891-<br>65 | 25 in 1 BOTTLE; Type 0: Not a Combination Product | 01/11/2024              |                       |  |
| 4 | NDC:16837-891-<br>66 | 50 in 1 BOTTLE; Type 0: Not a Combination Product | 12/14/2023              |                       |  |

| Marketing Information |   |                         |                       |
|-----------------------|---|-------------------------|-----------------------|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |
| NDA                   | NDA020958                                   | 03/01/2009              |                       |
|                       |   |                         |                       |

# Labeler - Kenvue Brands LLC (118772437)

Revised: 11/2024 Kenvue Brands LLC