

**PEPCID COMPLETE- famotidine, calcium carbonate, and magnesium hydroxide tablet, chewable**

**Navajo Manufacturing Company Inc**

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**Pepcid Complete**

***Drug Facts***

| <b><i>Active ingredients (in each chewable tablet)</i></b> | <b><i>Purposes</i></b> |
|--|------------------------|
| 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, croscopovidone, D&C red no. 7 calcium lake, dextrose excipient, FD&C blue no. 1 aluminum lake, FD&C red no. 40 aluminum lake, flavors, gum arabic, hydroxypropyl cellulose, hypromellose, lactose monohydrate, magnesium stearate, maltodextrin, mineral oil, modified starch, sucralose

## Questions or comments?

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

## PRINCIPAL DISPLAY PANEL



## PEPCID COMPLETE

famotidine, calcium carbonate, and magnesium hydroxide tablet, chewable

### Product Information

|                         |                |                    |                              |
|-------------------------|----------------|--------------------|------------------------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:67751-202(NDC:16837-298) |
| 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 CARBONATE                               | 800 mg               |                    |
| MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S) (HYDROXIDE ION - UNII:9159UV381P) |  | MAGNESIUM HYDROXIDE                             | 165 mg               |                    |
|  |  |   |                      |                    |
| Inactive Ingredients   |  |   |                      |                    |
| Ingredient Name  |  |   | Strength             |                    |
| CELLULOSE ACETATE (UNII: 3J2P07GVB6)                                     |  |   |                      |                    |
| STARCH, CORN (UNII: O8232NY3SJ)  |  |   |                      |                    |
| CROSPVIDONE (15 MPAS AT 5%) (UNII: 68401960MK)                           |  |   |                      |                    |
| DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)                            |  |   |                      |                    |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)                                       |  |   |                      |                    |
| ALUMINUM OXIDE (UNII: LMI26O6933)  |  |   |                      |                    |
| FD&C RED NO. 40 (UNII: WZB9127XOA)                                       |  |   |                      |                    |
| D&C RED NO. 7 (UNII: ECW0LZ41X8)   |  |   |                      |                    |
| ACACIA (UNII: 5C5403N26O)  |  |   |                      |                    |
| HYDROXYPROPYL CELLULOSE (70000 WAMW) (UNII: 66O7AQV0RT)                  |  |   |                      |                    |
| 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  | purple                                   | Score   | no score             |                    |
| Shape  | ROUND                                    | Size  | 18mm                 |                    |
| Flavor   | BERRY                                    | Imprint Code                                    | P                    |                    |
| Contains   |  |   |                      |                    |
|  |  |   |                      |                    |
| Packaging  |  |   |                      |                    |
| #  | Item Code                                | Package Description                             | Marketing Start Date | Marketing End Date |
| 1  | NDC:67751-202-02                         | 2 in 1 CARTON                                   | 08/06/2020           |                    |
| 1  |  | 1 in 1 POUCH; Type 0: Not a Combination Product |                      |                    |
| 2  | NDC:67751-202-01                         | 1 in 1 CARTON                                   | 08/06/2020           |                    |
| 2  |  | 1 in 1 POUCH; Type 0: Not a Combination Product |                      |                    |
|  |  |   |                      |                    |
| Marketing Information  |  |   |                      |                    |
| Marketing Category   | Application Number or Monograph Citation | Marketing Start Date                            | Marketing End Date   |                    |
| NDA  | NDA020958                                | 08/06/2020                                      |                      |                    |
|  |  |   |                      |                    |

**Labeler** - Navajo Manufacturing Company Inc (091917799)

| Establishment                     |         |           |  |
|-----------------------------------|---------|-----------|--|
| Name                              | Address | ID/FEI    | Business Operations                    |
| Navajo Manufacturing Company Inc. |         | 136941411 | relabel(67751-202) , repack(67751-202) |

Revised: 8/2020

Navajo Manufacturing Company Inc