

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

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
- keep the carton. It contains important information.
- store at 20°-25°C (68°-77°F)
- protect from moisture
- **do not use if pouch is torn or damaged**

Inactive ingredients

cellulose acetate, corn starch, crospovidone, D&C red no.7 calcium lake, dextrose excipient, FD&C blue no.1aluminum 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?

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

Repackaged and distributed by:

**Select Corporation 1433 Wainwright Way,
Carrollton, TX 75007, 877-244-4400, M-F 9am-5pm,
from a product manufactured by
JOHNSON & JOHNSON CONSUMER INC.**

Distributed by:

JOHNSON & JOHNSON CONSUMER INC.

McNeil Consumer Healthcare Division

Fort Washington, PA 19034 USA

PRINCIPAL DISPLAY PANEL - 20 Packet Carton

DUAL ACTION

Pepcid®

Complete®

Acid Reducer + Antacid

Famotidine 10mg-Acid reducer

Calcium carbonate 800mg-Antacid

Magnesium hydroxide 165mg-Antacid

Just One Tablet!

Relieves Heartburn Due
to Acid Indigestion

Berry Flavor

20

Packets of
1 Chewable
Tablet

DUAL ACTION
Pepcid[®] Complete[®]
 Acid Reducer + Antacid

Just One Tablet!
 Relieves Heartburn Due to Acid Indigestion

Berry Flavor

20 Packets of 1 Chewable Tablet



DUAL ACTION
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 Relieves Heartburn Due to Acid Indigestion



Berry Flavor

20 Packets of 1 Chewable Tablet

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Berry Flavor

20 Packets of 1 Chewable Tablet




TO OPEN
 PUSH IN TAB AND PULL OUT

20 PACKETS OF 1 CHEWABLE TABLET

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OPEN FLAP FOR COMPLETE DRUG FACTS

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, caffeine, chocolate, alcohol, and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking

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US Patent Nos. 6,814,978



2001948071

PEPCID COMPLETE

famotidine, calcium carbonate, and magnesium hydroxide tablet, chewable

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:52904-948(NDC:16837-246) |
| 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 |
|--|----------|
| STARCH, CORN (UNII: O8232NY3SJ) | |
| corn syrup (UNII: 9G5L16BK6N) | |
| crospovidone (120 .mu.m) (UNII: 68401960MK) | |
| dextrose, unspecified form (UNII: IY9XDZ35W2) | |
| FD&C yellow no. 5 (UNII: I753WB2F1M) | |
| aluminum oxide (UNII: LMI26O6933) | |
| FD&C yellow no. 6 (UNII: H77VEI93A8) | |
| acacia (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) | |
| triacetin (UNII: XHX3C3X673) | |
| cellulose acetate (UNII: 3J2P07GVB6) | |

Product Characteristics

| | | | |
|-----------------|-------------------------------|---------------------|----------|
| Color | YELLOW | Score | no score |
| Shape | ROUND | Size | 17mm |
| Flavor | FRUIT (tropical fruit flavor) | Imprint Code | P |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:52904-948-03 | 1 in 1 BLISTER PACK | 01/01/2009 | |
| 1 | | 1 in 1 POUCH; Type 0: Not a Combination Product | | |
| 2 | NDC:52904-948-07 | 2 in 1 BLISTER PACK | 01/01/2009 | |
| 2 | | 1 in 1 POUCH; Type 0: Not a Combination Product | | |
| 3 | NDC:52904-948-20 | 20 in 1 CARTON | 01/01/2009 | |
| 3 | | 1 in 1 POUCH; Type 0: Not a Combination Product | | |
| 4 | NDC:52904-948-25 | 25 in 1 CARTON | 01/01/2009 | |
| 4 | | 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 | 01/01/2009 | |

Labeler - Select Corporation (053805599)