PEPCID COMPLETE- famotidine, calcium carbonate, and magnesium hydroxide tablet, chewable
Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division

Pepcid Complete

Drug Facts

Active ingredients (in each chewable tablet)  

<table>
<thead>
<tr>
<th>Active Ingredient</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Famotidine 10 mg</td>
<td>Acid reducer</td>
</tr>
<tr>
<td>Calcium carbonate 800 mg</td>
<td>Antacid</td>
</tr>
<tr>
<td>Magnesium hydroxide 165 mg</td>
<td>Antacid</td>
</tr>
</tbody>
</table>

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, 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
NDC 16837-298-25
See New Warnings
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
Berry Flavor
actual size
25 Chewable Tablets
PEPCID COMPLETE
famotidine, calcium carbonate, and magnesium hydroxide tablet, chewable

Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>HUMAN OTC DRUG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Route of Administration</td>
<td>ORAL</td>
</tr>
</tbody>
</table>

Active Ingredient/Active Moiety

Drug Facts

**Active ingredients**
- Famotidine 10 mg
- Calcium carbonate 400 mg
- Magnesium hydroxide 165 mg

**Purposes**
- Antacid

**Uses**
- Relieves heartburn associated with acid indigestion and sour stomach

**Warnings**
- Do not use if you are allergic to famotidine or other acid reducers.
- Do not use if you have:
  - Peptic ulcer or irritable bowel syndrome.
  - Peptic ulcer disease.
- Do not use if you have had heartburn over 3 months. This may be a sign of a more serious condition.
- Do not use if you have heartburn with light-headedness, sweating, or dizziness.
- Do not use if you have chest pain or shoulder pain with shortness of breath, swelling, pain spreading to arm, neck or shoulder, or light-headedness.
- Do not use if you have frequent chest pain.
- Do not use if you have frequent, persistent, or severe heartburn.
- Do not use if you have unexplained weight loss.
- Do not use if you have kidney disease.

**Precautions**
- Do not use if you are pregnant or breastfeeding.
- Do not take if you have a history of allergy to any of the ingredients.
- Do not take if you have liver or kidney disease.

**Dosage and Administration**
- Take 1 tablet every 4 hours as needed.
- Do not exceed more than 12 tablets in 24 hours.

**Overdose**
- If you take too much, contact a Poison Control Center right away (1-800-222-1222).

**Interactions**
- Do not take with any other medicines without consulting your doctor or pharmacist.

**Side Effects**
- Common:
  - Constipation.
  - Diarrhea.
- Rare:
  - Rash.

**Additional Information**
- Keep out of reach of children.
- Store at 20-25°C (68-77°F).
- Store in airtight container.

**Questions or Comments?**
- Call 1-800-256-4000 (toll-free) or 1-212-273-8765 (collect).

**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.
### Ingredient Name

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Famotidine</strong> (UNII: 5QZO15J2Z8) (Famotidine - UNII:5QZO15J2Z8)</td>
<td>Famotidine</td>
<td>10 mg</td>
</tr>
<tr>
<td><strong>Calcium carbonate</strong> (UNII: H0G379FGK) (Carbonate ion - UNII:7UJQ5OPE7D)</td>
<td>Calcium carbonate</td>
<td>800 mg</td>
</tr>
<tr>
<td><strong>Magnesium hydroxide</strong> (UNII: NBZ3QY004S) (Hydroxide ion - UNII:9159UV381P)</td>
<td>Magnesium hydroxide</td>
<td>165 mg</td>
</tr>
</tbody>
</table>

### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>cellulose acetate (UNII: 3J2P07GVB6)</td>
<td></td>
</tr>
<tr>
<td>starch, corn (UNII: O8232NY3SJ)</td>
<td></td>
</tr>
<tr>
<td>crospovidone (15 MPAS AT 5%) (UNII: 68401960MK)</td>
<td></td>
</tr>
<tr>
<td>dextrose, unspecified form (UNII: F9XDZ35W2)</td>
<td></td>
</tr>
<tr>
<td>FD&amp;C Blue No. 1 (UNII: HBR47K3TBDD)</td>
<td></td>
</tr>
<tr>
<td>aluminum oxide (UNII: LM26O69333)</td>
<td></td>
</tr>
<tr>
<td>FD&amp;C Red No. 40 (UNII: WZB9127XOA)</td>
<td></td>
</tr>
<tr>
<td>D&amp;C Red No. 7 (UNII: ECW0LZ41X8)</td>
<td></td>
</tr>
<tr>
<td>acacia (UNII: 5C5403N26O)</td>
<td></td>
</tr>
<tr>
<td>hydroxypropyl cellulose (70000 WAMW) (UNII: 66O7AQV0RT)</td>
<td></td>
</tr>
<tr>
<td>hypromellose, unspecified (UNII: 3NXW29V3WO)</td>
<td></td>
</tr>
<tr>
<td>lactose monohydrate (UNII: EWQ57Q815X)</td>
<td></td>
</tr>
<tr>
<td>magnesium stearate (UNII: 70097M5B0)</td>
<td></td>
</tr>
<tr>
<td>maltodextrin (UNII: 7CVR7L4A2D)</td>
<td></td>
</tr>
<tr>
<td>mineral oil (UNII: T5L8T28FGP)</td>
<td></td>
</tr>
<tr>
<td>sucralose (UNII: 96K6UQ3ZD4)</td>
<td></td>
</tr>
</tbody>
</table>

### Product Characteristics

<table>
<thead>
<tr>
<th>Color</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>PURPLE</td>
<td>no score</td>
</tr>
<tr>
<td>Shape</td>
<td>Size</td>
</tr>
<tr>
<td>ROUND</td>
<td>18 mm</td>
</tr>
<tr>
<td>Flavor</td>
<td>Imprint Code</td>
</tr>
<tr>
<td>BERRY</td>
<td>P</td>
</tr>
<tr>
<td>Contains</td>
<td></td>
</tr>
</tbody>
</table>

### Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:16837-298-12</td>
<td>100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product</td>
<td>03/01/2009</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>NDC:16837-298-25</td>
<td>25 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product</td>
<td>03/01/2009</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>NDC:16837-298-50</td>
<td>50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product</td>
<td>03/01/2009</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>NDC:16837-298-65</td>
<td>2500 in 1 CARTON</td>
<td>06/15/2020</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
<td>1 in 1 POUCH; Type 0: Not a Combination Product</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>NDC:16837-298-67</td>
<td>4 in 1 CARTON</td>
<td>06/15/2020</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>NDC:16837-298-68</td>
<td>8 in 1 CARTON</td>
<td>06/15/2020</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td></td>
<td>1 in 1 POUCH; Type 0: Not a Combination Product</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA</td>
<td>NDA020958</td>
<td>03/01/2009</td>
<td></td>
</tr>
</tbody>
</table>

Labeler - Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division (878046358)

Revised: 2/2020

Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division