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

Pepcid Complete

Drug Facts

<table>
<thead>
<tr>
<th>Active ingredients (in each chewable tablet)</th>
<th>Purposes</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 "SAFETY SEAL®" is broken or missing

Inactive ingredients
cellulose acetate, corn starch, crospovidone, D&C yellow no. 10 aluminum lake, dextrose excipient,
FD&C blue no. 1 aluminum lake, flavors, gum arabic, hydroxypropyl cellulose, hypromellose, lactose
monohydrate, magnesium stearate, maltodextrin, mineral oil, sucralose

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

PRINCIPAL DISPLAY PANEL
See New Warnings
NDC 16837-891-50
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
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

Drug Facts

Active Ingredients (in each chewable tablet)
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:
- 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.
  - For more than 14 days.
- Keep out of reach of children.

Drug Facts (continued)

Ask a doctor before use if you have:
- Nausea or vomiting
- Stomach pain
- Kidney disease

Stop use and ask a doctor if:
- Your heartburn continues or worsens
- You need to take this product for more than 14 days

Contains:
- Carbomer, corn starch, crospovidone, FD&C Blue No. 1, FD&C Yellow No. 1, FD&C Red No. 40, gelatin, lactose monohydrate, magnesium stearate, maltodextrin, mineral oil, sucrose.

Inactive ingredients:
- Carbomer, corn starch, crospovidone, FD&C Blue No. 1, FD&C Yellow No. 1, FD&C Red No. 40, gelatin, lactose monohydrate, magnesium stearate, maltodextrin, mineral oil, sucrose.

Questions or comments? Call 1-800-755-4000 (toll-free) or 215-273-8715 (collect)

Directions:
- Adults and children 12 years and over: chew 1 tablet while on an empty stomach.
- Do not swallow whole. Chew completely.
- Do not exceed 2 tablets daily.

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

For Complete Directions and Warnings

Do not use if foil inner seal imprinted with "SAFETY SEAL®" is broken or missing.
# PEPCID COMPLETE
famotidine, calcium carbonate, and magnesium hydroxide tablet, chewable

## Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HUMAN OTC DRUG</td>
<td>NDC:16837-891</td>
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</table>

<table>
<thead>
<tr>
<th>Route of Administration</th>
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<tbody>
<tr>
<td>ORAL</td>
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## Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
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<tbody>
<tr>
<td>famotidine</td>
<td>famotidine</td>
<td>10 mg</td>
</tr>
<tr>
<td>calcium carbonate</td>
<td>calcium carbonate</td>
<td>800 mg</td>
</tr>
<tr>
<td>magnesium hydroxide</td>
<td>magnesium hydroxide</td>
<td>165 mg</td>
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## Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
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<tbody>
<tr>
<td>cellulose acetate</td>
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</tr>
<tr>
<td>starch, corn</td>
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<tr>
<td>crospovidone</td>
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<tr>
<td>D&amp;C yellow no. 10</td>
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<td>aluminum oxide</td>
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<tr>
<td>Dextrose, Unspecified form</td>
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<td>FD&amp;C blue no. 1</td>
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<tr>
<td>acacia</td>
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<td>lactose monohydrate</td>
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<td>magnesium stearate</td>
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<td>maltodextrin</td>
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<tr>
<td>mineral oil</td>
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<td>sucralose</td>
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## Product Characteristics

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<tr>
<th>Color</th>
<th>Score</th>
<th>Shape</th>
<th>Size</th>
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<tbody>
<tr>
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<tr>
<td>Flavor</td>
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## Packaging

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<tr>
<th>#</th>
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<th>Package Description</th>
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<tr>
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<td>25 in 1 BOTTLE; Type 0: Not a Combination Product</td>
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<td>2</td>
<td>NDC:16837-891-50</td>
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### Marketing Information

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<tr>
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<th>Marketing End Date</th>
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<tr>
<td>NDA</td>
<td>NDA020958</td>
<td>03/01/2009</td>
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#### Labeler

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

Revised: 7/2019

Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division