

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

**Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division**

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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, 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

NDC 16837-298-25  
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Distributed by:  
JOHNSON & JOHNSON CONSUMER INC.  
McNeil Consumer Healthcare Division  
Fort Washington, PA 19034 USA  
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US Patent No. 6,814,973

**Drug Facts (continued)**

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**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

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Acid Reducer + Antacid  
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Magnesium hydroxide 165 mg per tablet  
**25 Chewable Tablets**

Shown actual size

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US Patent No. 6,814,973

## PEPCID COMPLETE

famotidine, calcium carbonate, and magnesium hydroxide tablet, chewable

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:16837-298
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Famotidine</b> (UNII: 5QZO15J2Z8) (Famotidine - UNII:5QZO15J2Z8)	Famotidine	10 mg
<b>Calcium carbonate</b> (UNII: H0G9379FGK) (Carbonate ion - UNII:7UJQ5OPE7D)	Calcium carbonate	800 mg
<b>Magnesium hydroxide</b> (UNII: NBZ3QY004S) (Hydroxide ion - UNII:9159UV381P)	Magnesium hydroxide	165 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>cellulose acetate</b> (UNII: 3J2P07GVB6)	
<b>starch, corn</b> (UNII: O8232NY3SJ)	
<b>crospovidone (15 MPAS AT 5%)</b> (UNII: 68401960MK)	
<b>dextrose, unspecified form</b> (UNII: IY9XDZ35W2)	
<b>FD&amp;C Blue No. 1</b> (UNII: HBR47K3TBD)	
<b>aluminum oxide</b> (UNII: LMI26O6933)	
<b>FD&amp;C Red No. 40</b> (UNII: WZB9127XOA)	
<b>D&amp;C Red No. 7</b> (UNII: ECW0LZ41X8)	
<b>acacia</b> (UNII: 5C5403N26O)	
<b>hydroxypropyl cellulose (70000 WAMW)</b> (UNII: 66O7AQV0RT)	
<b>hypromellose, unspecified</b> (UNII: 3NXW29V3WO)	
<b>lactose monohydrate</b> (UNII: EWQ57Q815X)	
<b>magnesium stearate</b> (UNII: 70097M61B0)	
<b>maltodextrin</b> (UNII: 7CVR7L4A2D)	
<b>mineral oil</b> (UNII: T5L8T28FGP)	
<b>sucralose</b> (UNII: 96K6UQ3ZD4)	

### Product Characteristics

<b>Color</b>	PURPLE	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	18mm
<b>Flavor</b>	BERRY	<b>Imprint Code</b>	P
<b>Contains</b>			

### Packaging

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

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

Revised: 2/2020

Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division