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

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# **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
- 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, dextrose excipient, FD&C blue no. 1 aluminum lake, flavors, gum arabic, hydroxypropyl cellulose, hypromellose, lactose monohydrate, magnesium stearate, maltodextrin, mineral oil, sucralose, yellow iron oxide

# **Questions or comments?**

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

#### PRINCIPAL DISPLAY PANEL

NDC 16837-891-66

**DUAL ACTION** 

Pepcid ®

Complete

Famotidine 10 mg-Acid reducer

Calcium carbonate 800 mg-Antacid

Magnesium hydroxide 165 mg-Antacid

Just One Tablet!

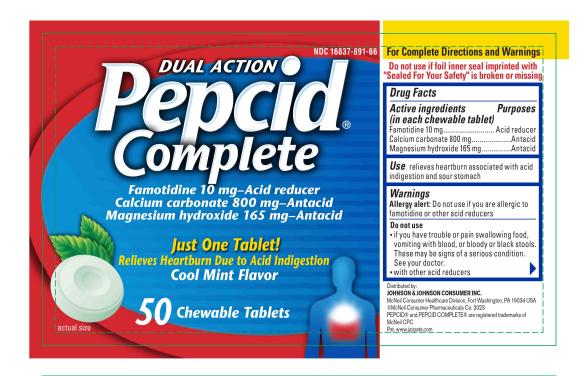
Relieves Heartburn Due to Acid Indigestion

Cool Mint Flavor

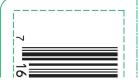
50

Chewable Tablets

actual size



#### Drug Facts (continued) 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 kidnev 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:





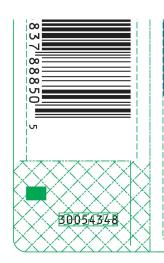
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Acid Reducer + Antacid Famotidine 10 mg per tablet Calcium carbonate 800 mg per tablet Magnesium hydroxide 165 mg per tablet



Shown actual size

**50 Chewable Tablets** Distributed by: JOHNSON & JOHNSON CONSUMER INC.

McNeil Consumer Healthcare Division, Fort Washington, PA 19034 USA 
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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

# **PEPCID COMPLETE**

famotidine, calcium carbonate, and magnesium hydroxide tablet, chewable

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:16837-891	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
FAMOTIDINE (UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8)	FAMOTIDINE	10 mg		
CALCIUM CARBONATE (UNII: H0G9379FGK) (CARBONATE ION - UNII: 7UJQ50PE7D)	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)			
CROSPOVIDONE (UNII: 2S7830E561)			
FERRIC OXIDE YELLOW (UNII: EX43802MRT)			
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)			
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)			
<b>ACACIA</b> (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)			

Product Characteristics			
Color	green	Score	no score
Shape	ROUND	Size	18mm
Flavor	MINT	Imprint Code	Р
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16837-891- 25	25 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2009	
2	NDC:16837-891- 50	50 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2009	
3	NDC:16837-891- 65	25 in 1 BOTTLE; Type 0: Not a Combination Product	01/11/2024	
4	NDC:16837-891- 66	50 in 1 BOTTLE; Type 0: Not a Combination Product	12/14/2023	

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. (878046358)

Revised: 2/2024 Johnson & Johnson Consumer Inc.