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

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
- contains FD&C yellow no. 5 (tartrazine) as a color additive
- 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, corn syrup solids, crospovidone, dextrose excipient, FD&C yellow no. 5 aluminum lake (tartrazine), FD&C yellow no. 6 aluminum lake, flavors, gum arabic, hydroxypropyl cellulose, hypromellose, lactose monohydrate, magnesium stearate, maltodextrin, mineral oil, sucralose, triacetin

Questions or comments?

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

PRINCIPAL DISPLAY PANEL

NDC 16837-246-25

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

Tropical Fruit Flavor

actual size

25

Chewable Tablets

For Complete Directions and Warnings

Do not use if foil inner seal imprinted with "Sealed For Your Safety" is broken or missing

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Distributed by:
JOHNSON & JOHNSON CONSUMER INC.
McNeil Consumer Healthcare Division, Fort Washington, PA 19034 USA

Drug Facts (continued)

Warnings

Allergy alert: Do not use if you are allergic to famotidine or other acid reducers

Do not use
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- with other acid reducers

Ask a doctor before use if you have
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Drug Facts (continued)

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Questions or comments?
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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
Acid Reducer + Antacid
Famotidine 10 mg per tablet
Calcium carbonate 800 mg per tablet
Magnesium hydroxide 165 mg per tablet
25 Chewable Tablets


Shown actual size

Distributed by: **JOHNSON & JOHNSON CONSUMER INC.**
McNeil Consumer Healthcare Division, Fort Washington, PA 19034 USA

PEPCID COMPLETE

famotidine, calcium carbonate, and magnesium hydroxide tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	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:16837-246-05	5 in 1 CARTON	01/01/2009	03/31/2013
1		1 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:16837-246-08	8 in 1 CARTON	01/01/2009	03/31/2012
2		1 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:16837-246-25	25 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2009	
4	NDC:16837-246-26	25 in 1 TRAY	01/01/2009	04/11/2016
4		1 in 1 POUCH; Type 0: Not a Combination Product		
5	NDC:16837-	2500 in 1 TRAY	01/01/2009	03/31/2014

5	246-27	2500 in 1 TRAY	01/01/2009	03/31/2014
5		1 in 1 POUCH; Type 0: Not a Combination Product		
6	NDC:16837-246-28	2500 in 1 TRAY	01/01/2009	03/31/2013
6		1 in 1 POUCH; Type 0: Not a Combination Product		
7	NDC:16837-246-29	25 in 1 TRAY	01/01/2009	05/31/2013
7		1 in 1 POUCH; Type 0: Not a Combination Product		
8	NDC:16837-246-50	50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2009	
9	NDC:16837-246-36	1 in 1 CARTON	01/01/2009	01/24/2014
9		35 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
10	NDC:16837-246-64	65 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2009	03/24/2014

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020958	01/01/2009	

Labeler - Johnson & Johnson Consumer Inc. (878046358)

Revised: 2/2024 Johnson & Johnson Consumer Inc.