PEPCID COMPLETE- famotidine, calcium carbonate, and magnesium hydroxide tablet, chewable R J General Corporation

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
- keep this carton. It contains important information
- store at 20°-25°C (68°-77°F)
- protect from moisture
- do not use if pouch is torn or damaged

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)

Distributed by:

JOHNSON & JOHNSON CONSUMER INC.

McNeil Consumer Healthcare Division

For Washington, PA 19034 USA

Repackaged and distributed by: RJ General

2024 Northwest Drive, Cincinnati OH 45231

Do Not Use if the sealed child resistant pouch is broken or torn

PRINCIPAL DISPLAY PANEL

NDC 70264-034-01

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

50 Chewable Tablets



PEPCID COMPLETE

famotidine, calcium carbonate, and magnesium hydroxide tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70264-034(NDC:16837-298)
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: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)				
D&C RED NO. 7 (UNII: ECWOLZ41X8)				
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)				
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)				
ACACIA (UNII: 5C5403N260)				
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	purple	Score	no score
Shape	ROUND	Size	18mm
Flavor	BERRY	Imprint Code	P
Contains			

F	Packaging			
#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70264-034-	50 in 1 CARTON; Type 0: Not a Combination Product	12/28/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020958	01/09/2022	

Labeler - R J General Corporation (122542830)

Establishment			
Name	Address	ID/FEI	Business Operations
R J General Corporation		122542830	repack(70264-034)

Revised: 10/2023 R J General Corporation