

PEPCID COMPLETE- famotidine, calcium carbonate, magnesium hydroxide tablet, chewable
JC World Bell Wholesale Co., Inc.

Pepcid Complete

Drug Facts

Active ingredients (in each chewable tablet)

Famotidine 10 mg
Calcium carbonate 800 mg
Magnesium hydroxide 165 mg

Purposes

Acid reducer
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 the 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**

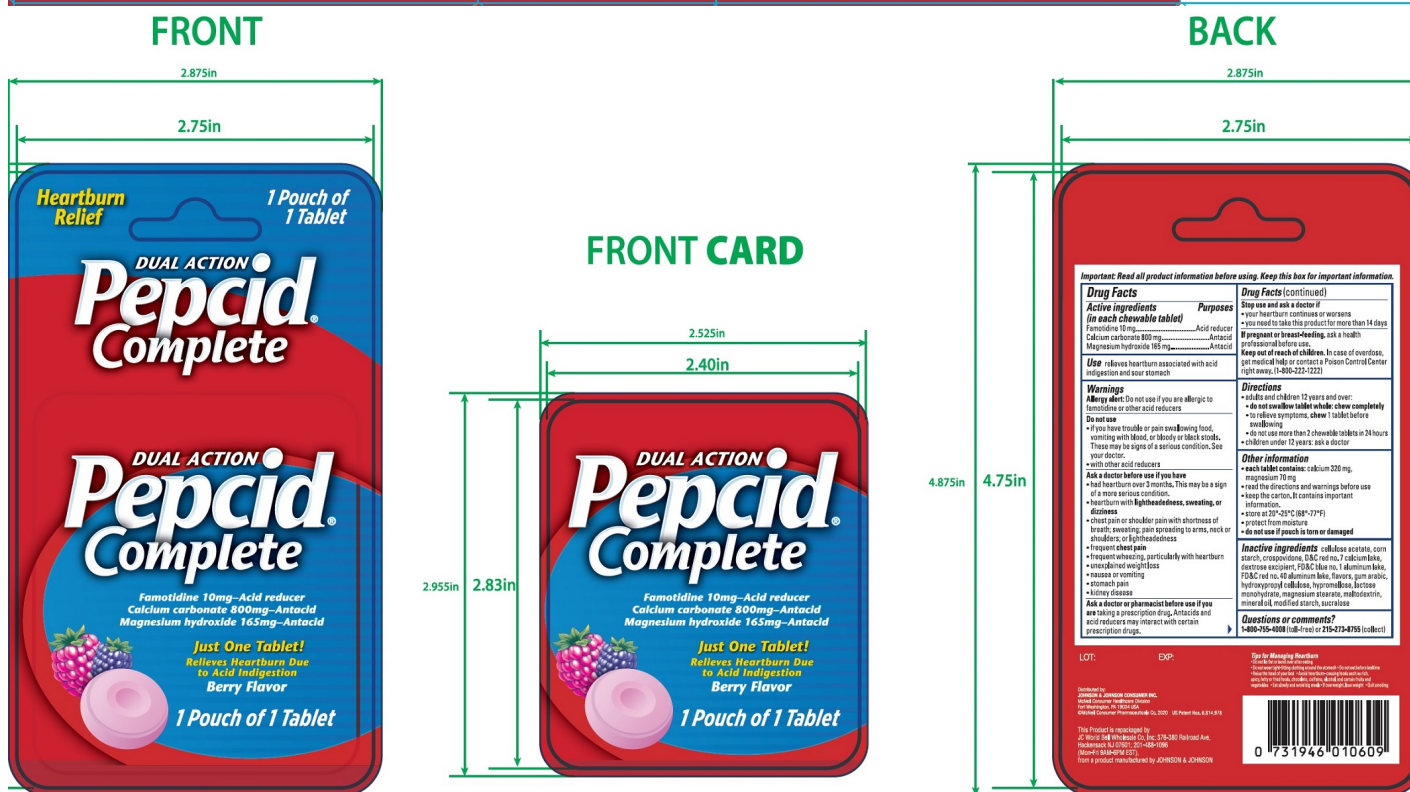
Inactive ingredients

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

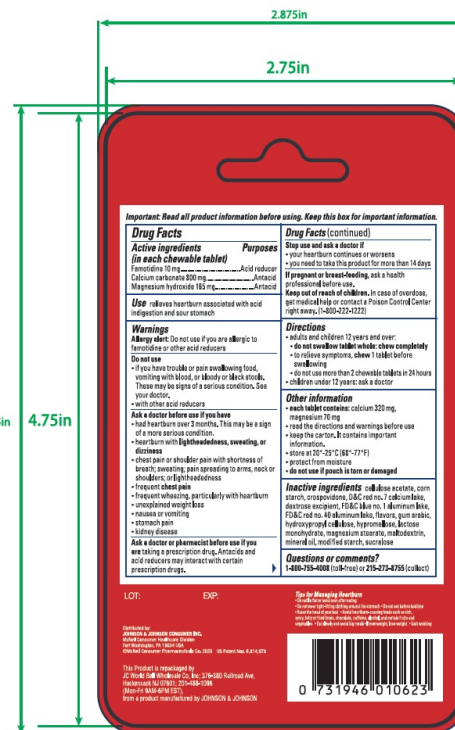
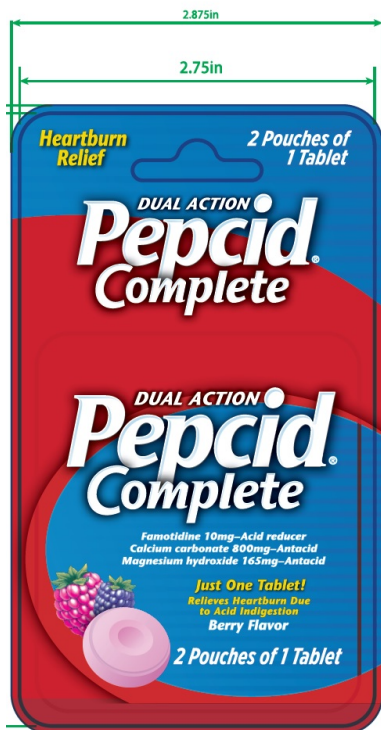
Questions or comments?

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

Package Labeling:50269-016-01



Package Labeling:50269-016-02



Package Labeling:Inner Package3



PEPCID COMPLETE

famotidine, calcium carbonate, magnesium hydroxide tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50269-016(NDC:16837-298)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK) (CARBONATE ION - UNII:7UJQ5OPE7D)	CALCIUM CARBONATE	800 mg
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S) (HYDROXIDE ION - UNII:9159UV381P)	MAGNESIUM HYDROXIDE	165 mg
FAMOTIDINE (UNII: 5QZ015J2Z8) (FAMOTIDINE - UNII:5QZ015J2Z8)	FAMOTIDINE	10 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE ACETATE (UNII: 3J2P07GVB6)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPVIDONE (15 MPAS AT 5%) (UNII: 68401960MK)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	

FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
ACACIA (UNII: 5C5403N26O)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I3O)	
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			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50269-016-01	6 in 1 BOX	09/01/2020	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:50269-016-02	6 in 1 BOX	09/01/2020	
2		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:50269-016-25	25 in 1 BOX	09/01/2020	
3		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	09/01/2020	

Labeler - JC World Bell Wholesale Co., Inc. (805257581)

Establishment

Name	Address	ID/FEI	Business Operations
Johnson & Johnson Consumer Inc.		878046358	manufacture(50269-016)

Establishment

Name	Address	ID/FEI	Business Operations
JC World Bell Wholesale Co., Inc.		805257581	repack(50269-016)

Revised: 12/2023

JC World Bell Wholesale Co., Inc.