

COMPLETE DUAL ACTION- famotidine, calcium carbonate and magnesium hydroxide tablet, chewable

HyVee Inc

Hy-Vee, Inc. Dual Action 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 330 mg; magnesium 80 mg
- Phenylketonurics: Contains Phenylalanine 2 mg per tablet
- 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

Inactive ingredients

anhydrous lactose, artificial berry flavor, aspartame, D&C red no. 7 calcium lake, dextrans, FD&C blue no. 1 aluminum lake, FD&C red no. 40 aluminum lake, glyceryl monostearate, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyacrylate dispersion, polysorbate 80, povidone, pregelatinized starch, sodium starch glycolate, talc

Questions or comments?

1-800-289-8343

Principal Display Panel

Hy•Vee®

Compare To Pepcid Complete® Active Ingredients

Dual Action Complete

Famotidine 10 mg/Calcium Carbonate 800 mg/Magnesium Hydroxide 165 mg Tablets (Chewable)

Acid Reducer + Antacid

Just One Tablet! Relieves Heartburn Due to Acid Indigestion

Berry Flavor

actual size

SEE NEW WARNINGS

50 CHEWABLE TABLETS



0 54208 4218 0

Drug Facts DO NOT USE IF PRINTED FOIL UNDER CAP IS BROKEN OR MISSING

Active ingredients (in each chewable tablet)

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

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- stomach pain
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***Compare To Pepcid Complete® Active Ingredients**

NDC 42507-321-50

Dual Action Complete

Famotidine 10 mg/Calcium Carbonate 800 mg/Magnesium Hydroxide 165 mg Tablets (Chewable)

Acid Reducer + Antacid



Just One Tablet!
Relieves Heartburn
Due to Acid Indigestion

Berry Flavor actual size

50

SEE NEW WARNINGS **CHEWABLE TABLETS**

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

GLUTEN FREE

LOT: 32371 2H F3
EXP: 3/23/17

Drug Facts (continued)

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- Pfeniktonics: Contains Pfeniktonine 2 mg per tablet
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COMPLETE DUAL ACTION

famotidine, calcium carbonate and magnesium hydroxide tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42507-321
Route of Administration	ORAL		

Drug Facts (continued)

Inactive ingredients anhydrous lactose, artificial berry flavor, aspartame, D&C red no. 7 calcium lake, dextrates, FD&C blue no. 1 aluminum lake, FD&C red no. 40 aluminum lake, glyceryl monostearate, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyacrylate dispersion, polybutene S0, polyvinone, pregelatinized starch, sodium starch glycolate, talc

Questions or comments? 1-800-280-8343

*This product is not manufactured or distributed by Kenne Inc., owner of the registered trademark Pepcid Complete®, U.S. Pat. No. D801,175

DISTRIBUTED BY HY-VEE, INC.
 WEST DES MOINES, IA 50266 PERA1025
<http://hyvee.info/gVCuaJ>
 SATISFACTION GUARANTEED
 CALL 1-800-280-8343
www.hy-vee.com

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 CATION - UNII:2M83C4R6ZB)	CALCIUM CARBONATE	800 mg
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838, HYDROXIDE ION - UNII:9159UV381P)	MAGNESIUM HYDROXIDE	165 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
ASPARTAME (UNII: Z0H242BBR1)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
DEXTRATES (UNII: G263MI44RU)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
FD&C RED NO. 40 ALUMINUM LAKE (UNII: 6T47AS764T)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	PINK (mottled)	Score	no score
Shape	ROUND (bi-layered)	Size	17mm
Flavor	BERRY	Imprint Code	L321
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42507-321-63	25 in 1 BOTTLE; Type 0: Not a Combination Product	08/11/2008	04/01/2014
2	NDC:42507-321-50	50 in 1 BOTTLE; Type 0: Not a Combination Product	02/25/2026	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077355	08/11/2008	

