DG HEALTH ACID REDUCER COMPLETE- famotidine, calcium carbonate and magnesium hydroxide tablet, chewable

Dolgencorp, LLC

Dolgencorp, LLC Acid Reducer 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

Ask a doctor or pharmacist before use if you are

presently taking a prescription drug. Antacids 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 label. 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, 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, polysorbate 80, povidone, pregelatinized starch, sodium starch glycolate, talc

Questions or comments?

1-888-309-9030

Principal Display Panel

Compare to the active ingredients of Pepcid Complete®

Dual Action

Acid Reducer 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

25 Chewable Tablets

Berry Flavor



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

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Purposes

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DOLGENCORP, LLC
TOOMISSIONRIDGE
GOODLETTSVILLE,
TN 37072 USA

Satisfaction Guarantee d! (888) 309-9030

This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of Pepcid Complete®. luestions or comments?1-888-309-9030

monostearate, lactose monohydrate, magnesim stearate, microcrystalline cellulose, polyacrylate dispersion, polysorbate 80, povidone, pregelatinized starch, sodium starch discolate to pregelatinized starch, sodium starch Inactive ingredients anhydrous lactose, artificial berry flavor, aspartame, D&C red no. 7 calcium lake, dextrates, FD&C blue no. 1 aluminum lake, plyceryl

Drug Facts (continued

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

Drug Facts

Active ingredients (in each chewable tablet)

Famotidine 10 mg. . .Acid reducer Calcium carbonate 800 mg...... Magnesium hydroxide 165 mg......

Use relieves heartburn associated with acid indigestion and sour stomach

Warnings

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■ 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
- Ask a doctor or pharmacist before use if you are presently taking a prescription drug. Antacids may interact with certain prescription drugs.

Stop use and ask a doctor if

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Keep out of reach of children. In case of overdose, get



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Drug Facts (continued)

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DG HEALTH ACID REDUCER COMPLETE

famotidine, calcium carbonate and magnesium hydroxide tablet, chewable

Product Information

HUMAN OTC DRUG NDC:55910-808 Product Type Item Code (Source)

CATION - UNII:2M83C4R6ZB)

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
FAMO TIDINE (UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8)	FAMOTIDINE	10 mg	
MAGNESIUM HYDRO XIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838, HYDRO XIDE ION - UNII:9159UV381P)	MAGNESIUM HYDRO XIDE	165 mg	

800 mg

CARBONATE

CALCIUM CARBONATE (UNII: H0 G9379 FGK) (CARBONATE ION - UNII:7UJQ50 PE7D, CALCIUM CALCIUM

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDROUS LACTOSE (UNII: 3SY5LH9 PMK)		
ASPARTAME (UNII: Z0H242BBR1)		
D&C RED NO. 7 (UNII: ECW0LZ41X8)		
DEXTRATES (UNII: G263MI44RU)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)		
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
POLYSORBATE 80 (UNII: 6OZP39ZG8H)		
PO VIDO NE (UNII: FZ989 GH94E)		
TALC (UNII: 7SEV7J4R1U)		

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

l	Packaging				
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
ı	1 NDC:55910-808-63	25 in 1 BOTTLE; Type 0: Not a Combination Product	12/27/2018		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA077355	12/27/20 18		

Revised: 12/2018 Dolgencorp, LLC