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

American Sales Company

American Sales Company 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
- 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, 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?

1-800-719-9260

Principal Display Panel

Compare to the active ingredients in Pepcid Complete®

ACID REDUCER COMPLETE

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

Acid Reducer + Antacid

Berry Flavor

Actual Size

Just One Tablet! Relieves Heartburn Due to Acid Indigestion

Dual-Action
See New Warnings
OUR PHARMACISTS RECOMMEND
25 CHEWABLE TABLETS







CAREONE ACID REDUCER COMPLETE

famotidine, calcium carbonate and magnesium hydroxide tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-409
Route of Administration	ORAL		

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:T6 V3LHY838, HYDRO XIDE ION - UNII:9159 UV381P)	MAGNESIUM HYDRO XIDE	165 mg	
CALCIUM CARBONATE (UNII: H0G9379FGK) (CARBONATE ION - UNII:7UJQ50PE7D, CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CARBONATE	800 mg	

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)		
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)		
POLYSORBATE 80 (UNII: 6OZP39ZG8H)		
PO VIDONE, UNSPECIFIED (UNII: FZ989GH94E)		
TALC (UNII: 7SEV7J4R1U)		

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

ı	Packaging				
l	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1	NDC:41520-409-63	25 in 1 BOTTLE; Type 0: Not a Combination Product	09/29/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077355	09/29/2016	

Labeler - American Sales Company (809183973)

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