

**TOPCARE DUAL ACTION COMPLETE- famotidine, calcium carbonate and magnesium hydroxide tablet, chewable**  
**Topco Associates LLC**

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**Topco Associates LLC. 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?**

**1-888-423-0139**

### **Principal Display Panel**

# COMPARE TO PEPCID COMPLETE® ACTIVE INGREDIENTS

Dual Action Complete

SEE NEW WARNINGS

FAOTIDINE 10 mg, CALCIUM CARBONATE 800 mg

MAGNESIUM HYDROXIDE 165 mg TABLETS (CHEWABLE)

ACID REDUCER + ANTACID

Just One Tablet Relieves Heartburn Due to Acid Indigestion

actual size

25 CHEWABLE TABLETS

BERRY FLAVOR

TOPCARE DUAL ACTION COMPLETE			
famotidine, calcium carbonate and magnesium hydroxide tablet, chewable			
Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-616
<b>Route of Administration</b>	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:7UJQ5OPE7D, CALCIUM CATION - UNII:2M83C4R6ZB)		CALCIUM CARBONATE	800 mg

<b>MAGNESIUM HYDROXIDE</b> (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838, HYDROXIDE ION - UNII:9159UV381P)	<b>MAGNESIUM HYDROXIDE</b>	165 mg
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<b>Inactive Ingredients</b>	
<b>Ingredient Name</b>	<b>Strength</b>
<b>ANHYDROUS LACTOSE</b> (UNII: 3SY5LH9PMK)	
<b>ASPARTAME</b> (UNII: Z0H242BBR1)	
<b>D&amp;C RED NO. 7</b> (UNII: ECW0LZ41X8)	
<b>DEXTRATES</b> (UNII: G263MI44RU)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	

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

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-616-63	25 in 1 BOTTLE; Type 0: Not a Combination Product	02/29/2016	
2	NDC:36800-616-71	50 in 1 BOTTLE; Type 0: Not a Combination Product	02/29/2016	

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077355	02/29/2016	

**Labeler** - Topco Associates LLC (006935977)