

**DUAL ACTION COMPLETE- famotidine, calcium carbonate, magnesium hydroxide tablet, chewable**  
**Meijer Distribution Inc**

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**Meijer Distribution, 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, aspartame, dextrates, ferric oxide, glyceryl monostearate, lactose monohydrate, magnesium stearate, microcrystalline cellulose, natural peppermint flavor, polyacrylate dispersion, polysorbate 80, povidone, pregelatinized starch, sodium starch glycolate, talc

### **Questions or comments?**

**1-800-719-9260**

### **Principal Display Panel**

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

SEE NEW WARNINGS

HEARTBURN RELIEF | Just One Tablet!

Relieves Heartburn Due to Acid Indigestion

50 Chewable Tablets

actual size

Cool Mint Flavor

**Drug Facts**  
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 Famotidine 10 mg.....Acid reducer  
 Calcium carbonate 800 mg.....Antacid  
 Magnesium hydroxide 165 mg.....Antacid

**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

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**SEE NEW WARNINGS HEARTBURN RELIEF | Just One Tablet! Relieves Heartburn Due to Acid Indigestion**

**50 Chewable Tablets**  
 actual size  
 Cool Mint Flavor

**Compare to Pepcid Complete\* active ingredients\***

**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

**Drug Facts (continued)**  
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 ■ you need to take this product for more than 14 days  
**If pregnant or breast-feeding,** ask a health professional before use.  
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**Other information**  
 ■ each tablet contains: calcium 330 mg; magnesium 80 mg  
 ■ Phenylethanamine: Contains Phenylethanamine 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

**Drug Facts (continued)**  
**Inactive ingredients** anhydrous lactose, aspartame, dextrose, ferric oxide, glyceryl monostearate, lactose monohydrate, magnesium stearate, microcrystalline cellulose, natural peppermint flavor, polyacrylate dispersion, polyacrylate 80, polydioxane, pregelatinized starch, sodium starch glycolate, talc

**Questions or comments? 1-800-719-9280**

\*This product is a manufactured, distributed by Johnson & Johnson Corporation, owner of the registered trademark Pepcid Complete®. U.S. Pat. No. D 801, 175

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**GF GLUTEN FREE**

**OUR QUALITY GUARANTEE**

## DUAL ACTION COMPLETE

famotidine, calcium carbonate, magnesium hydroxide tablet, chewable

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41250-690
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>FAMOTIDINE</b> (UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8)	FAMOTIDINE	10 mg
<b>CALCIUM CARBONATE</b> (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)	MAGNESIUM HYDROXIDE	165 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS LACTOSE</b> (UNII: 3SY5LH9PMK)	
<b>ASPARTAME</b> (UNII: Z0H242BBR1)	
<b>DEXTRATES</b> (UNII: G263MI44RU)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<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)	

### Product Characteristics

<b>Color</b>	ORANGE (PEACH WTH WHITE SPECKLES)	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	18mm
<b>Flavor</b>	MINT	<b>Imprint Code</b>	L546
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41250-690-71	50 in 1 BOTTLE; Type 0: Not a Combination Product	01/26/2016	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077355	01/26/2016	

**Labeler** - Meijer Distribution Inc (006959555)