DUAL ACTION COMPLETE- famotidine, calcium carbonate and magnesium hydroxide tablet, chewable
Publix Super Markets Inc

Publix Super Markets, 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 68-77˚F (20-25˚C)
- 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

Package/Label Principal Display Panel

SEE NEW WARNINGS

BERRY FLAVOR

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

ACTUAL SIZE

Compare to active ingredients in Pepcid Complete®

25 CHEWABLE TABLETS

DUAL ACTION COMPLETE

famotidine, calcium carbonate and magnesium hydroxide tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:56062-263
Route of Administration	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
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 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
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:56062-263-63	25 in 1 BOTTLE; Type 0: Not a Combination Product	11/06/2018	
2	NDC:56062-263-71	50 in 1 BOTTLE; Type 0: Not a Combination Product	11/06/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077355	11/06/2018	

Labeler - Publix Super Markets Inc (006922009)

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