

DUO FUSION- famotidine, calcium carbonate, magnesium hydroxide tablet, chewable
Boehringer Ingelheim Pharmaceuticals, Inc.

DUOFUSION™

Famotidine 10 mg/Calcium Carbonate 800 mg
Magnesium Hydroxide 165 mg Tablets
Berry Flavor

Drug Facts

<i>Active ingredients</i> <i>(in each chewable tablet)</i>	<i>Purpose</i>
Famotidine 10 mg	Acid Reducer
Calcium carbonate 800 mg	Antacid
Magnesium hydroxide 165 mg	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 70 mg
- Phenylketonurics: Contains **phenylalanine** 2.2 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, glycerol monostearate, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyacrylate dispersion, polysorbate 80, povidone, pregelatinized starch, sodium starch glycolate, talc

Questions? Call **1-888-285-9159** (English/Spanish) M – F, 8:30 – 5 EST, or visit **www.DuoFusion.com**

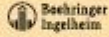
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DUO Fusion™ 20 ct Label
NDC: 0597-0315-97

Drug Facts (continued)

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? Call 1-888-285-9159 (English/Spanish), M-F, 8:30-5 EST, or visit www.DuoFusion.com



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Pharmaceuticals, Inc., Ridgefield, CT
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Actual size

L6877C P038827-003 5/16

- 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 carbon fruits and vegetables
 - Eat slowly and avoid big meals
 - If overweight, lose weight
 - Quit smoking

323C9 D6 F2

From the makers of **Zantac®**

DUO FUSION™

Famotidine 10 mg/Calcium Carbonate 800 mg
Magnesium Hydroxide 165 mg Tablets

ACID REDUCER + ANTACID

DUAL ACTION™

JUST 1 TABLET RELIEVES HEARTBURN DUE TO ACID INDIGESTION

20 Berry CHEWABLE Tablets

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

Drug Facts

Active ingredients (in each chewable tablet)	Purpose
Famotidine 10 mg	Acid reducer
Calcium carbonate 800 mg	Antacid
Magnesium hydroxide 165 mg	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 unexplained 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

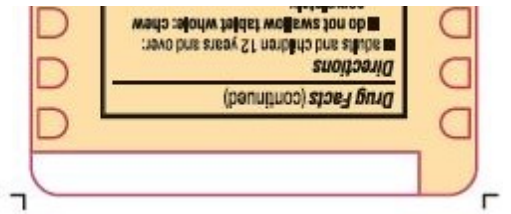
If pregnant or breast-feeding, ask a health professional before use.

Other information

- each tablet contains: calcium 330 mg; magnesium 70 mg Phenylephrine: Contains phenylephrine 2.2 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

Concave

- 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

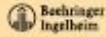


DUO Fusion™ 34 ct Label
NDC: 0597-0315-36

Drug Facts (continued)

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? Call 1-888-285-9199 (English/Spanish), M–F, 8:30–5 EST, or visit www.DuoFusion.com



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Actual size

L9971C P038825-003 5/16

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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From the makers of **Zantac®**

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Famotidine 10 mg/Calcium Carbonate 800 mg/Magnesium Hydroxide 165 mg Tablets

DUAL ACTION

ACID REDUCER + ANTACID

JUST 1 TABLET RELIEVES HEARTBURN DUE TO ACID INDIGESTION

34 Berry CHEWABLE TABLETS

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

Drug Facts

Active ingredients	Purpose
(in each chewable tablet)	
Famotidine 10 mg	Acid reducer
Calcium carbonate 800 mg	Antacid
Magnesium hydroxide 165 mg	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, fainting, chest pain, frequent wheezing, or trouble breathing. Ask your doctor if you have heartburn, especially if you have lost weight, or if you have 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 at 1-800-234-3530

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 70 mg; Phenylephrine 2.5 mg per tablet
- Contains phenylephrine 2.5 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

Calcium Carbonate (UNII: H0G9379FGK) (CARBONATE ION - UNII:7UJQ5OPE7D)	Calcium Carbonate	800 mg
Magnesium Hydroxide (UNII: NBZ3QY004S) (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: HBR47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
ALUMINUM OXIDE (UNII: LM26O6933)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONES (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	PURPLE	Score	no score
Shape	ROUND	Size	17mm
Flavor	BERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0597-0315-97	20 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2016	
2	NDC:0597-0315-36	34 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2016	
3	NDC:0597-0315-08	55 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077355	03/01/2016	

Labeler - Boehringer Ingelheim Pharmaceuticals, Inc. (603175944)

Registrant - Boehringer Ingelheim Pharmaceuticals, Inc. (603175944)

Establishment

Name	Address	ID/FEI	Business Operations
Perrigo		006013346	PACK(0597-0315) , MANUFACTURE(0597-0315)

Revised: 9/2016

Boehringer Ingelheim Pharmaceuticals, Inc.