

DULCOGAS- simethicone tablet, chewable
Boehringer Ingelheim Pharmaceuticals, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredient (in each tablet)

Simethicone (USP) 125 mg

Purpose

Antigas

Use for the relief of pressure, bloating, and fullness commonly referred to as gas

Warnings

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 (1-800-222-1222) right away.

Directions

- adults: chew 1 or 2 tablets as needed after meals and at bedtime
- do not exceed 4 tablets in 24 hours except under the advice and supervision of a physician

Other information

- **do not use if individual blister unit is open or torn**
- store at 20-25°C (68-77°F)
- protect from excessive humidity

Wild Berry

Inactive ingredients D&C red #27 aluminum lake, D&C red #30 aluminum lake, dextrates hydrated, FD&C blue #1 aluminum lake, flavors, propylene glycol, silicon dioxide, sorbitol, starch, stearic acid, talc, triacetin, tribasic calcium phosphate

Tangy Citrus

Inactive ingredients citric acid, D&C yellow #10 aluminum lake, dextrates hydrated, flavors, silicon dioxide, sorbitol, starch, stearic acid, talc, tribasic calcium phosphate

Sabor Tropical

Inactive ingredients dextrates hydrated, FD&C yellow #6 aluminum lake, flavors, maltodextrin, medium chain triglycerides, silicon dioxide, sorbitol, starch, stearic acid, talc, tribasic calcium phosphate

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

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DulcoGas Wild Berry Simethicone 125 mg

DulcoGas Tropical Simethicone 125 mg



DULCOGAS

simethicone tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0597-0170
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	125 mg

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
DEXTRATES (UNII: G263MI44RU)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SORBITOL (UNII: 506T60A25R)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	

Product Characteristics

Color	YELLOW	Score	2 pieces
Shape	ROUND	Size	14mm
Flavor	CITRUS (Tangy)	Imprint Code	DULCO;GAS
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0597-0170-88	3 in 1 CARTON	02/28/2014	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0597-0170-37	5 in 1 CARTON	02/28/2014	
2		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part332	02/28/2014	

DULCOGAS

simethicone tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0597-0165
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	125 mg

Inactive Ingredients

Ingredient Name	Strength
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
DEXTRATES (UNII: G263M44RU)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SORBITOL (UNII: 506T60A25R)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	

TRIACETIN (UNII: XHX3C3X673)

TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)

STEARIC ACID (UNII: 4ELV7Z65AP)

Product Characteristics

Color	PURPLE	Score	2 pieces
Shape	ROUND	Size	14mm
Flavor	BERRY (Wild)	Imprint Code	DULCO;GAS
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0597-0165-88	3 in 1 CARTON	02/28/2014	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0597-0165-37	5 in 1 CARTON	02/28/2014	
2		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:0597-0165-36	1 in 1 CARTON	02/28/2014	11/30/2015
3		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part332	02/28/2014	

DULCOGAS

simethicone tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0597-0186
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	125 mg

Inactive Ingredients

Ingredient Name	Strength
DEXTRATES (UNII: G263M44RU)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
ALUMINUM OXIDE (UNII: LM26O6933)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SORBITOL (UNII: 506T60A25R)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	

Product Characteristics

Color	ORANGE	Score	2 pieces
Shape	ROUND	Size	14mm
Flavor	TROPICAL FRUIT PUNCH	Imprint Code	DULCO;GAS
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0597-0186-88	3 in 1 CARTON	04/10/2014	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part332	04/10/2014	

Labeler - Boehringer Ingelheim Pharmaceuticals, Inc. (603175944)

Registrant - Boehringer Ingelheim Pharmaceuticals, Inc. (603175944)

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Boehringer Ingelheim Pharmaceuticals, Inc.