

GAS RELIEF- simethicone capsule, liquid filled
PuraCap Pharmaceutical LLC

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.

Gas Relief

Drug Facts

Active ingredient (in each softgel)

Simethicone 125 mg

Purpose

Antigas

Uses

for the relief of

- pressure, bloating, and fullness commonly referred to as gas

Warnings

Keep out of reach of children.

Directions

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

Other information

- store at room temperature 15°-30°C (59°-86°F)
- protect from light, heat and moisture

Inactive ingredients

D&C yellow #10, FD&C blue #1, FD&C red #40, gelatin, glycerin, peppermint oil, purified water, white edible ink

Questions or comments?

Call toll free: **1-800-719-9260**

PRINCIPAL DISPLAY PANEL

EXTRA STRENGTH GAS RELIEF

SIMETHICONE 125 mg ANTIGAS 20 Softgels

NDC 51013-423-08

Compare to the active ingredient in Gas-X® Extra Strength Softgels

Harris Teeter™

Gas Relief

NDC 51013-423-08

Simethicone 125 mg – Antigas

EXTRA STRENGTH

Quickly Relieves

- Gas • Pressure
- Bloating • Discomfort

20 Softgels

Actual Size

Gas Relief

Simethicone 125 mg – Antigas

Harris Teeter™

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*This product is not manufactured or distributed by Novartis Consumer Health Inc., owner of the registered trademark Gas-X®.

PROUDLY DISTRIBUTED BY:
HARRIS TEETER, LLC
MATTHEWS, NC 28105

 your *plus* guarantee.

If you are not 100% satisfied with this product, simply return it with your VIC card for a full refund. Plus we will replace it with a like item of your choice. For full details: 1-800-432-6111 or harristeeter.com.



Made in China
HT04-00



Gas Relief
Simethicone 125 mg – Antigas

GAS RELIEF

simethicone capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:510 13-423
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 YELLOW NO. 10 (UNII: 35SW5USQ3G)				
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
GELATIN (UNII: 2G86QN327L)				
GLYCERIN (UNII: PDC6A3C0OX)				
PEPPERMINT OIL (UNII: AV092KU4JH)				
WATER (UNII: 059QF0KO0R)				
Product Characteristics				
Color	green (opaque)	Score	no score	
Shape	capsule (oval)	Size	10mm	
Flavor		Imprint Code	PC2	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:510 13-423-08	2 in 1 CARTON	11/22/2017	
1		10 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	11/22/2017		

Labeler - PuraCap Pharmaceutical LLC (962106329)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(510 13-423) , analysis(510 13-423)

Revised: 11/2017

PuraCap Pharmaceutical LLC