

**GAS RELIEF EXTRA STRENGTH- simethicone capsule, liquid filled
TOP CARE (Topco Associates 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.

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

If pregnant or breast-feeding,

ask a health professional before use.

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 unless directed by a doctor

Other information

- store at controlled room temperature 20-25°C (68-77°F)
- protect from light, heat, and moisture

Inactive ingredients

D&C yellow #10, edible ink, FD&C blue #1, FD&C red #40, gelatin, glycerin, medium-chain triglycerides*, peppermint oil, purified water, sorbitan, sorbitol, titanium dioxide

*may contain this ingredient

Questions or comments?

Call toll free **1-888-423-0139**

Principal Display Panel

EXTRA STRENGTH Gas Relief

SIMETHICONE, 125 mg

Relieves bloating, pressure, fullness and gas

COMPARE TO GAS-X® active ingredient†

SOFTGELS

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

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

DISTRIBUTED BY TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60007

topcare@topco.com

Product Label

NDC-36800-242-30

TopCare®

EXTRA STRENGTH

Gas Relief

SIMETHICONE, 125 mg

- **Relieves bloating, pressure, fullness and gas**



COMPARE TO GAS-X® active ingredient†

30 SOFTGELS

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

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Lot No.:

Exp. Date:

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ELK GROVE VILLAGE, IL 60007
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QUESTIONS? 1-888-423-0139
topcare@topco.com



This TOPCARE® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.



PLD-C
FC001606

Top Care Extra Strength Gas Relief Softgel

GAS RELIEF EXTRA STRENGTH

simethicone capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-242
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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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)				
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)				
PEPPERMINT OIL (UNII: AV092KU4JH)				
WATER (UNII: 059QF0KO0R)				
SORBITAN (UNII: 6O92ICV9RU)				
SORBITOL (UNII: 506T60A25R)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	GREEN	Score	no score	
Shape	OVAL	Size	9mm	
Flavor		Imprint Code	PO;S1;SCU	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-242-30	2 in 1 CARTON		
1		15 in 1 BLISTER PACK		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part347	10/30/2013		

Labeler - TOP CARE (Topco Associates LLC) (006935977)

Revised: 10/2013

TOP CARE (Topco Associates LLC)