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 of 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 between 15-30°C (59-86°F)
- do not refrigerate
- protect from light, heat, and moisture

Inactive ingredients

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

*contain one or more of these ingredients

Questions or comments?

Call toll free 1-888-423-0139

Principal Display Panel

COMPARE TO GAS-X® EXTRA STRENGTH ACTIVE INGREDIENT[†]

EXTRA STRENGTH

Gas Relief

ANTI-GAS/SIMETHICONE, 125 mg

FAST RELIEF OF:

- Bloating
- Pressure
- Fullness & Gas

SOFTGELS

[†]This product is not manufactured or distributed by GSK Consumer Healthcare, distributor of Gas-X® Extra Strength.

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

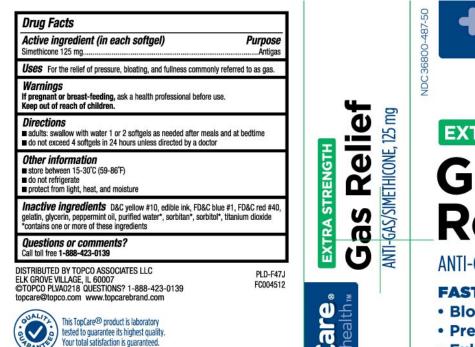
DISTRIBUTED BY TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60007

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www.topcarebrand.com

Product Label



COMPARE TO GAS-X® EXTRA STRENGTH **ACTIVE INGREDIENT**† **EXTRA STRENGTH** Gas Relief ANTI-GAS/SIMETHICONE, 125 mg **FAST RELIEF OF:** Bloating Pressure Fullness & Gas actual

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50 SOFTGELS

size



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Lot No .: Exp. Date:

TOPCARE HEALTH Extra Strength Gas Relief

GAS RELIEF EXTRA STRENGTH

simethicone capsule, liquid filled

Inactive Ingredients

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:36800-487 **Route of Administration ORAL**

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10)	DIMETHICONE	125 mg

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6092ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics				
Color	green	Score	no score	
Shape	OVAL	Size	9mm	
Flavor		Imprint Code	PO;SCU;L125	
Contains				

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:36800-487- 30	30 in 1 CARTON	08/31/2016				
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product					
2	NDC:36800-487- 50	50 in 1 CARTON	08/31/2016				
2		1 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	part347	08/31/2016		

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

Revised: 12/2022 TOP CARE (Topco Associates LLC)