GAS RELIEF EXTRA STRENGTH- simethicone capsule, liquid filled TOP CARE (Topco Associates LLC)

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 except under the advice and supervision of a physican

Other information

- store between 20-25°C (68-77°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, mannitol, peppermint oil, purified water, sorbitan, sorbitol, titanium dioxide

Questions or comments?

Call toll free 1-888-423-0139

Principal Display Panel

COMPARE TO THE ACTIVE INGREDIENT IN GAS-X® EXTRA STRENGTH†

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



TOPCARE HEALTH Gas Relief

GAS RELIEF EXTRA STRENGTH

simethicone capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-197
Route of Administration	ORAL		

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

125 mg

Inactive Ingredients	
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)	
MANNITOL (UNII: 30WL53L36A)	

Product Characterist	oduct Characteristics		
Color	green	Score	no score
Shape	OVAL	Size	9mm
Flavor		Imprint Code	PO
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-197- 30	30 in 1 CARTON	11/29/2019	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:36800-197- 50	50 in 1 CARTON	11/29/2019	
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 Drug	M016	11/29/2019	

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

Revised: 11/2024 TOP CARE (Topco Associates LLC)