GAS RELIEF ULTRA 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 180 mg

Purpose

Antigas

Uses

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

Warnings

If pregnant or breast-feeding,

ask a health care 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 2 softgels in 24 hours except under the advice and supervision of a physician

Other information

- store between 15-30°C (59-86°F)
- protect from heat and moisture

Inactive ingredients

edible white printing ink, FD&C yellow #6, gelatin, glycerin, purified water.

Questions or comments?

Call toll free 1-888-423-0139

Principal Display Panel

COMPARE TO GAS-X® ULTRA STRENGTH ACTIVE INGREDIENT*

ULTRA STRENGTH

Gas Relief

ANTI-GAS/SIMETHICONE, 180 mg

FAST RELIEF OF:

- Bloating
- Pressure
- Fullness & Gas

SOFTGELS

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.

*This product is not manufactured or distributed by GSK Consumer Healthcare, distributor of Gas-X $\ensuremath{\mathbb{R}}$

DISTRIBUTED BY TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60007

topcare@topco.com

Product Label



GAS RELIEF ULTRA STRENGTH simethicone capsule, liquid filled										
Product Information										
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:36800-125						
Route of Administration	ORAL									
Active Ingredient/Active Moiety										
Ingre	Basis of Strength		Strength							
DIMETHICONE (UNII: 92RU3N3Y10	DIMETHICONE		180 mg							
Inactive Ingredients										

		Strength							
FD&C YELLOW N									
GELATIN (UNII: 2G	86QN327L)								
GLYCERIN (UNII: P									
WATER (UNII: 0590									
Product Char	acterist	ics							
Color		orange	Score		no score				
Shape		OVAL	Size		9mm				
Flavor	Imprint Code			S180					
Contains									
Packaging									
# Item Code		Package Description		Marketing Start Date	Marketing End Date				
1 NDC:36800- 125-50	5 in 1 CAR	RTON		10/04/2010					
10 in 1 BLISTER PACK; Type 0: Not a Combination Product									
Marketing Information									
•									
Marketing Category	Арр	lication Number or Monograph Citation		Marketing Start Date	: Marketing End Date				
OTC monograph fir	nal part332	rt332		10/04/2010					

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

Revised: 12/2022

TOP CARE (Topco Associates LLC)