

**GAS RELIEF ULTRA STRENGTH- dimethicone capsule, liquid filled
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.

Gas Relief Ultra Strength

Drug Facts

Active ingredient (in each softgel)

Simethicone 180 mg

Purpose

Antigas

Use

for the relief of

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

Warnings

Keep out of reach of children.

Directions

- adults and children 12 years and older: 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 20-25°C (68-77°F)
- protect from heat and moisture

Inactive ingredients

FD&C yellow #6, gelatin, glycerin, peppermint oil, povidone, purified water, sorbitol sorbitan solution, titanium dioxide

Questions?

Call **1-888-423-0139**

PRINCIPAL DISPLAY PANEL - 50 Softgel Blister Pack Carton

NDC:36800-802-67

*Compare to the active ingredient
in Gas-X[®] Ultra Strength

Ultra Strength
Gas Relief
Softgels

ANTIGAS / SIMETHICONE 180mg

RELIEVES GAS FAST

- Pressure
- Bloating
- Discomfort

actual size

50 Softgels



GAS RELIEF ULTRA STRENGTH

dimethicone capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-324
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	180 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
Glycerin (UNII: PDC6A3C00X)	

Peppermint Oil (UNII: AV092KU4JH)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
WATER (UNII: 059QF0KO0R)	
Titanium Dioxide (UNII: 15FIX9V2JP)	

Product Characteristics

Color	ORANGE	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	792
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-324-05	2 in 1 CARTON	05/01/2021	
1		25 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	05/01/2021	

Labeler - TOPCO ASSOCIATES LLC (006935977)

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TOPCO ASSOCIATES LLC