GAS RELIEF EXTRA STRENGTH- simethicone capsule, liquid filled WinCo Foods, 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 1-800-824-1706 Monday-Friday 9AM-4PM MST

Principal Display Panel

**Compare to the active ingredient in GAS-X® EXTRA STRENGTH

EXTRA STRENGTH

Gas Relief

SIMETHICONE 125 mg / ANTIGAS

Fast Relief for:

Pressure, Bloating & Discomfort

Easy to Swallow

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:

WINCO FOODS, LLC, BOISE, ID 83704

www.wincofoods.com

Product Label





"Compare to the active ingredient in GAS-X® EXTRA STRENGTH



SIMETHICONE 125 mg/ANTIGAS

Fast Relief for: Pressure, Bloating & Discomfort

Easy to Swallow



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Lot / Exp.: Product of:

WINCO FOODS Extra Sttrength Gas Relief Softgels

GAS RELIEF EXTRA STRENGTH

WF1711 PLD-A47J FC004588

simethicone capsule, liquid filled

GUARANTEE Comments & Questions? 800-824-1706 www.wincofoods.com

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:67091-320 **Route of Administration ORAL**

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

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:67091- 320-30	2 in 1 CARTON	12/31/2017	05/31/2024			
1		15 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	12/31/2017	05/31/2024	

Labeler - WinCo Foods, LLC (056098817)

Revised: 11/2021 WinCo Foods, LLC