GAS RELIEF EXTRA STRENGTH- simethicone capsule, liquid filled Care One (American Sales Company)

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 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to the active ingredient in Gas-X® Extra Strength†

EXTRA STRENGTH

GAS RELIEF

Simethicone 125 mg Antigas

RELIEVES:

PRESSURE, BLOATING, FULLNESS, GAS

SOFTGELS

**This product is not manufactured or distributed GSK Comsumer 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.

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LANDOVER, MD 20785 • 1-877-846-9949

Product Label



CAREONE Extra Strength Gas Relief

GAS RELIEF EXTRA STRENGTH

simethicone capsule, liquid filled

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (So	ource)	NDC:415	20-487
Route of Administration	ORAL				
Active Ingredient/Active	Majaty				
Active Ingredient/Active Moiety					
Ingredient Name Basis of Strength Streng				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)	

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:41520-487- 30	30 in 1 CARTON	11/30/2016	02/28/2025			
1		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	11/30/2016	02/28/2025		

Labeler - Care One (American Sales Company) (809183973)

Revised: 11/2022 Care One (American Sales Company)