#### GAS RELIEF EXTRA STRENGTH- simethicone capsule, liquid filled Cardinal Health (Leader) 70000

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.

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#### **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 unless directed by a doctor

### Other information

- store between 15-30°C (59-86°)
- 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

\*contains one or more of these ingredients

### Questions or comments?

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

# **Principal Display Panel**

Extra Strength

## GAS RELIEF

Simethicone,125 mg | Antigas

For Relief of:

Pressure

Bloating

Discomfort

COMPARE TO GAS-X® EXTRA STRENGTH active ingredient\*\*

#### 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 CARDINAL HEALTH

DUBLIN, OHIO 43017

www.myleader.com 1-800-200-6313

**Product Label** 

Drug Facts	$\sim$	$\sim$	
Active ingredient (in each softgel) Purpose Simethicone 125 mgAntigas	Cừ	LEADER	
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.	LEADER	NDC 70000-0382-1	
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		Extra Strength	
Other information store between 15-30°C (59-86°F) do not refrigerate protect from light, heat, and moisture		<b>Gas Relief</b>	
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 *contains one or more of these ingredients		Simethicone, 125 mg   Antigas	
Questions or comments? Call 1-877-753-3935 Monday-Friday 9AM-5PM EST			
"This product is not manufactured or distributed by GSK Consumer Healthcare, distributor of Gas-X <sup>®</sup> Extra Strength.	<b>O</b>	COMPARE TO GAS-X <sup>®</sup> EXTRA	
© 2018 Cardinal Health. All Rights Reserved. CARDINAL HEALTH, the Cardinal Health		For Relief of: STRENGTH Pressure active ingredient**	
LOGO, LEADER, and the Leader LOGO are trademarks or registered trademarks of Cardinal Health. All other marks are the property of their respective owners.	f 💑	Bloating Discomfort Discomfort	
CardinalHealth™	N Len	Dack Oudraintee	
DISTRIBUTED BY CARDINAL HEALTH CIN 5450127 REV. 9/18 DUBLIN, 0HIO 43017 www.myleader.com 1-800-200-6313 Essential to Care <sup>™</sup> since 1979	xtra Strength	30 softgels	
All LEADER <sup>®</sup> Brand Products Have A 100% Money Back Guarantee Return to place of purchase if not satisfied. 0 PLD-A47J FC004959 2	ш		
		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.	
		Lot No.:	
		Exp. Date:	

LEADER Extra Strength Gas Relief

GAS RELIEF EXTRA S	TRENGTH					
simethicone capsule, liquid filled						
Product Information						
Product T ype	HUMAN OTC DRUG	Item Code (Source)		NDC:70000-0382		
Route of Administration	ORAL					
Active Ingredient/Active Moi	ety					
Ingredient Name Basis of S				Strength	Strength	
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O) DIMETHICON					125 mg	
Inactive Ingredients						
	Ingredient Name			Str	ength	
D&C YELLOW NO. 10 (UNII: 35SW5U	SQ3G)					

FD&C BLUE NO. 1 (UNII: H3	R47K3TBD)						
FD&C RED NO.40 (UNII: WZB9127XOA)							
GELATIN (UNII: 2G86QN327L)							
GLYCERIN (UNII: PDC6A3C0OX)							
PEPPERMINT OIL (UNII: AV092KU4JH)							
WATER (UNII: 059QF0KO0F							
SORBITAN (UNII: 6092ICV							
SORBITOL (UNII: 506T60A							
TITANIUM DIO XIDE (UNII: 1	15FIX9V2JP)						
Product Characteristi	rs						
Color	GREEN	Score		no score			
Shape	OVAL			9mm			
Flavor		Imprint Code		PO;SCU;L125			
Contains		Imprint Code		10,000,1120			
Contains							
Packaging							
# Item Code	Package I	Description	Marketing	Start Date	Marketing End Date		
NDC:70000-0382-1 30 in 1 CARTON		09/30/2018					
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		09/30/2018					

Labeler - Cardinal Health (Leader) 70000 (097537435)

Revised: 11/2019

Cardinal Health (Leader) 70000