

**GAS RELIEF ULTRA 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 180 mg

**Purpose**

Antiflatulent (Antigas)

**Use**

- relieves bloating, pressure, or fullness commonly referred to as gas

**Warnings**

**Stop use and ask a doctor if**

condition persists.

**If pregnant or breast-feeding,**

ask a health care professional before use.

**Keep out of reach of children.**

**Directions**

- swallow one or two softgels as needed after a meal
- do not exceed two softgels per day 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**

FD&C red #40\*,FD&C yellow # 6, gelatin, glycerin, purified water, white printing ink\*

\*contains one or more of these ingredients

### **Questions or comments?**

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

### **Principal Display Panel**

COMPARE TO PHAZYME® ULTRA STRENGTH active ingredient\*\*

Ultra Strength

Gas Relief

Simethicone, 180 mg | Antigas

For Relief of:

Gas

Pressure

Bloating

Discomfort

SOFTGELS

\*\*This product is not manufactured or distributed by C.B. Fleet Company Inc., distributor of Phazyme® Ultra Strength.

**TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.**

**DISTRIBUTED BY CARDINAL HEALTH**

**DUBLIN, OHIO 43017**

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

**Package Label**

**LEADER<sup>™</sup>**

**Drug Facts (continued)**

**Inactive ingredients** FD&C red #40\*, FD&C yellow #6, gelatin, glycerin, purified water, white printing ink\*  
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**LEADER<sup>™</sup>**

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**All LEADER<sup>™</sup> Brand Products Have A 100% Money Back Guarantee**

Return to place of purchase if not satisfied.

**LEADER<sup>™</sup>**

NDC 70000-0383-1

**Ultra Strength  
Gas Relief**

Simethicone, 180 mg | Antigas

For Relief of:  
Gas  
Pressure  
Bloating  
Discomfort



**COMPARE TO PHAZYME<sup>®</sup> ULTRA STRENGTH active ingredient\*\***

**100% Money Back Guarantee**

Actual Size  
**60 SOFTGELS**

**Drug Facts**

Active ingredient (in each softgel)	Purpose
Simethicone 180 mg.....	Antiflatulent (Antigas)

**Uses**  
■ relieves bloating, pressure, or fullness commonly referred to as gas

**Warnings**  
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**Other information**  
■ store between 15-30°C (59-86°F)  
■ protect from heat and moisture ▶

CIN 5450135      REV. 10/18



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PLD-A46G  
FC003889

Lot No.:  
Exp. Date:

## LEADER Ultra Strength Gas Relief

### GAS RELIEF ULTRA STRENGTH

simethicone capsule, liquid filled

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0383
<b>Route of Administration</b>	ORAL		

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	180 mg

#### Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	

<b>WATER</b> (UNII: 059QF0KO0R)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	

### Product Characteristics

<b>Color</b>	orange (Clear)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	12mm
<b>Flavor</b>		<b>Imprint Code</b>	S180;05A
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0383-1	1 in 1 BOX	11/09/2018	12/27/2024
1		60 in 1 BOTTLE, PLASTIC; 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	11/09/2018	12/27/2024

**Labeler** - Cardinal Health (Leader) 70000 (063997360)

Revised: 10/2022

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