

**ULTRA STRENGTH GAS RELIEF- simethicone capsule, liquid filled**  
**RELIABLE 1 LABORATORIES 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.*

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**Ultra Strength Gas Relief**

**Drug Facts**

**Active ingredient (in each softgel)**

Simethicone 180 mg

**Purpose**

Anti-gas

**Uses**

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

**Warnings**

**Stop use and ask a doctor if** condition persists

**Keep out of reach of children.**

**Directions**

- swallow 1 or 2 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 at room temperature 59° - 86°F (15° - 30°C)

**Inactive ingredients**

FD&C yellow#6, gelatin, glycerin, purified water and white edible ink

**Questions or comments?**

Call: **516-341-0666**

**PRINCIPAL DISPLAY PANEL**

Ultra Strength Gas Relief

Simethicone 180 mg Anti-gas 180 Softgels

NDC 69618-045-18

\*Compare to the active ingredient in PHAZYME<sup>®</sup> Ultra Strength

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**Reliable-1**  
LABORATORIES

**Ultra Strength Gas Relief**  
**Simethicone 180 mg**  
RELIEVES GAS FAST  
Bloating, Pressure, Discomfort

**180 SOFTGELS**

**Drug Facts**

**Active ingredient (in each softgel)**  
Simethicone 180 mg.....Anti-gas

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

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

**Warnings**  
Stop use and ask a doctor if condition persists  
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


**Drug Facts (continued under label)**

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL UNDER CAP IS BROKEN OR MISSING.**

\*Reliable-1 Laboratories LLC is not affiliated with the owner of the trademark PHAZYME®.

Distributed by:  
Reliable-1 Laboratories LLC  
Valley Stream, NY 11580  
www.reliable1labs.com

RE05-00  
Made in China

  
3 69618-04518 7

Lot No.:  
Exp. Date:

**Drug Facts (continued)**

**Other information**  
■ store at controlled room temperature 59° - 86°F (15° - 30°C)  
■ protect from heat and moisture

**Inactive ingredients**  
FD&C yellow#6, gelatin, glycerin, purified water and white edible ink

**Questions or comments?**  
Call 516-341-0666 8:30 am - 4:30 pm ET, Monday - Friday

## ULTRA STRENGTH GAS RELIEF

simethicone capsule, liquid filled

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69618-045
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 (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	

## Product Characteristics

<b>Color</b>	orange (clear)	<b>Score</b>	no score
<b>Shape</b>	capsule (oval)	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	PC3
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69618-045-18	180 in 1 BOTTLE; Type 0: Not a Combination Product	07/13/2017	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part332	07/13/2017	

**Labeler** - RELIABLE 1 LABORATORIES LLC (079718111)

## Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(69618-045) , analysis(69618-045)

Revised: 7/2017

RELIABLE 1 LABORATORIES LLC