

**GAS RELIEF- simethicone capsule, liquid filled**  
**PuraCap Pharmaceutical 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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**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 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 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 toll free: **1-855-215-8180**

**PRINCIPAL DISPLAY PANEL**

ULTRA STRENGTH Gas Relief

Simethicone 180 mg Antigas

NDC 51013-115-01

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



## GAS RELIEF

simethicone capsule, liquid filled

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:510 13-115
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: 059QF0KO0R)

### 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:510 13-115-01	1 in 1 CARTON	07/15/2016	
1		10 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	part332	07/15/2016	

**Labeler** - PuraCap Pharmaceutical LLC (962106329)

### Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(510 13-115) , analysis(510 13-115)

Revised: 7/2016

PuraCap Pharmaceutical LLC