

**MAXIMUM STRENGTH GAS RELIEF- simethicone capsule, liquid filled  
FOODHOLD U.S.A., 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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**MAXIMUM STRENGTH GAS RELIEF**

**Active ingredient (in each softgel)**

Simethicone 250 mg

**Purpose**

Anti-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 after a meal
- do not exceed two softgels per 24 hours except under the advice and supervision of a physician

**Other information**

- store at room temperature 59°-86°F (15°-30°C)

**Inactive ingredients**

D&C red #33, FD&C blue #1, gelatin, glycerin, purified water, and white edible ink

**Questions or comments?**

**Call: 1-855-215-8180**

**PRINCIPAL DISPLAY PANEL**

CAREONE MAXIMUM STRENGTH GAS RELIEF

SIMETHICONE 250 mg

Anti-gas

NDC 41520-983-02

Compare to the active ingredient in PHAZYME® Maximum Strength

## 12 Liquid-Filled SoftGels



### MAXIMUM STRENGTH GAS RELIEF

simethicone capsule, liquid filled

#### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-983
Route of Administration	ORAL		

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	250 mg

#### Inactive Ingredients

Ingredient Name	Strength

<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WATER</b> (UNII: 059QF0K00R)	

### Product Characteristics

<b>Color</b>	purple (clear)	<b>Score</b>	no score
<b>Shape</b>	capsule (oval)	<b>Size</b>	13mm
<b>Flavor</b>		<b>Imprint Code</b>	PC31
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-983-02	1 in 1 CARTON	10/05/2016	
1		12 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	10/05/2016	

**Labeler** - FOODHOLD U.S.A., LLC (809183973)

### Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(41520-983) , analysis(41520-983)

Revised: 10/2016

FOODHOLD U.S.A., LLC