

**SIMETHICONE- 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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**MAXIMUM STRENGTH GAS RELIEF**

**Active ingredient**

Simethicone 250 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 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 toll free: 1-855-215-8180

**Package/Label Principal Display Panel – Principal Display Panel**

NDC 51013-439-02

\*Compare to the active ingredient  
in PHAZYME® Maximum Strength

MAXIMUM STRENGTH **250 mg**

# **GAS RELIEF**

**ANTI-GAS** SIMETHICONE 250 mg

**RELIEVES GAS FAST**

BLOATING  
PRESSURE  
DISCOMFORT



ACTUAL SIZE

**12** SOFTGELS  
250 mg each

MAXIMUM STRENGTH **250 mg**  
**GAS RELIEF**

EACH DOSE IS INDIVIDUALLY SEALED IN A BLISTER PACK.  
DO NOT USE IF BLISTER UNIT IS TORN OR BROKEN.

LOT NO:

EXP DATE:

Package/Label Principal Display Panel – Drug Facts

**Drug Facts**

**Active ingredient (in each softgel)** **Purpose**  
Simethicone 250 mg.....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 toll free: 1-855-215-8180

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

Distributed By:  
COMPANY NAME  
ADDRESS  
Made in China



WG11-00

**MAXIMUM STRENGTH 250 mg**  
**GAS RELIEF**

**SIMETHICONE**

simethicone capsule, liquid filled

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51013-439
<b>Route of Administration</b>	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
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

### Product Characteristics

Color	PURPLE (Clear)	Score	no score
Shape	CAPSULE (Oval)	Size	13mm
Flavor		Imprint Code	PC31
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:510 13-439-02	1 in 1 CARTON	03/25/2019	
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	03/25/2019	

**Labeler** - PURACAP PHARMACEUTICAL LLC (962106329)

Revised: 3/2019

PURACAP PHARMACEUTICAL LLC