

**ULTRA STRENGTH 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.

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 toll free: **1-855-215-8180**

PRINCIPAL DISPLAY PANEL

Ultra Strength Gas Relief

Simethicone 180 mg Anti-gas 60 Softgels

NDC 51013-436-22

*Compare to the active ingredient in PHAZYME® Ultra Strength

NDC 51013-436-22

*Compare to the Active Ingredient
in PHAZYME® Ultra Strength

Ultra Strength

Gas Relief

SIMETHICONE 180 mg
ANTI-GAS

Relieves:

- Bloating
- Pressure
- Discomfort

Easy-to-Swallow Softgels



60 SOFTGELS (180 mg each)

Drug Facts

<i>Active ingredient (in each softgel)</i>	<i>Purpose</i>
Simethicone 180 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 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 controlled room temperature 15° - 30°C (59° - 86°F)
- protect from heat and moisture
- do not use if imprinted safety seal under cap is broken or missing

Inactive ingredients

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

Question or comments?

Call toll free: 1-XXX-XXX-XXXX

**DO NOT USE IF IMPRINTED SAFETY SEAL
UNDER CAP IS BROKEN OR MISSING**

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

Distributed by:
PuraCap Pharmaceutical LLC
20 Kingsbridge Road
Piscataway, NJ 08854
Made in China
CMB71-00

Ultra Strength Gas Relief

**SIMETHICONE 180 mg
ANTI-GAS**

Relieves:

- Bloating
- Pressure
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Easy-to-Swallow Softgels



60 SOFTGELS (180 mg each)

ULTRA STRENGTH GAS RELIEF

simethicone capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51013-436
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

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51013-436-22	1 in 1 CARTON	03/27/2018	
1		60 in 1 BOTTLE; 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	03/27/2018	

Labeler - PURACAP PHARMACEUTICAL LLC (962106329)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(51013-436) , analysis(51013-436)

Revised: 3/2018

PURACAP PHARMACEUTICAL LLC