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 51013-123-22

*Compare to the active ingredient in PHAZYME® Ultra Strength



Ultra Strength

Gas Relief

ANTI-GAS/SIMETHICONE 180 mg

60 SOFTGELS (180 mg each)





NDC 51013-123-22



*Compare to the Active Ingredient in PHAZYME® Ultra Strength

Ultra Strength

Gas Relie

ANTI-GAS/SIMETHICONE 180 mg

Easy to Swallow Softgels

For Fast Relief of Pressure, Bloating & Gas Distress



60 SOFTGELS (180 mg each)



*Compare to the Active Ingredient in PHAZYME® Ultra Strength



Ultra Strength

ANTI-GAS/SIMETHICONE 180 mg

Easy to Swallow Softgels

For Fast Relief of Pressure, Bloating & Gas Distress



60 SOFTGELS (180 mg each)

Drug Facts

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

Drug Facts (continued)

Inactive ingredients

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

Question 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®.

www.discount-drugmart.com DISTRIBUTED BY DRUG MART-FOOD FAIR MEDINA, OHIO 44256 Made in China

SATISFACTION GUARANTEED IF DISSATISFIED, RETURN UNUSED PORTION AND PACKAGE TO STORE WHERE PURCHASED, IF UNABLE TO RETURN TO STORE, SEND REASON FOR DISSATISFACTION, NAME, ADDRESS AND EMPTY PACKAGE TO: DISCOUNT DRUG MART, 211 COMMERCE DRIVE, MEDINA, OHIO 44256







NDC 51013-123-22

Ultra Strength

ANTI-GAS/SIMETHICONE 180 mg

Easy to Swallow Softgels



60 SOFTGELS (180 mg each)

WARNINGS AND PRODUCT INFORMATION

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

Active ingredien

Use relieves bloating, pressure or fullness commonly referred to as gas in each softgel) imethicone 180 mg.

Stop use and ask a doctor if condition persist Keep out of reach of children Directions

swallow one or two softgels as needed after a meal

under the advice and supervision of a physiciar do not exceed two softgels per day except

Inactive ingredients

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

IISTRIBUTED BY DRUG MART-FOOD FAIR

ULTRA STRENGTH GAS RELIEF

simethicone capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51013-123
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
DIMETHICO NE (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	10 mm
Flavor		Imprint Code	PC3
Contains			

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:51013-123-22	1 in 1 CARTON	07/17/2017		
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	07/17/2017	

Labeler - PuraCap Pharmaceutical LLC (962106329)

Establishment			
Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(51013-123), analysis(51013-123)

Revised: 7/2017 PuraCap Pharmaceutical LLC