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.

EXTRA STRENGTH GAS RELIEF

Drug Facts

Active ingredient (in each softgel)

Simethicone 125 mg

Purpose

Antigas

Uses

for the relief of
- pressure, bloating, and fullness commonly referred to as gas

Warnings

Keep out of reach of children.

Directions
- adults: swallow with water 1 or 2 softgels as needed after meals and at bedtime
- do not exceed 4 softgels in 24 hours except under the advice and supervision of a physician

Other information
- store at room temperature 15°-30°C (59°-86°F)
- protect from light, heat and moisture

Inactive ingredients

D&C yellow #10, FD&C blue #1, FD&C red #40, gelatin, glycerin, peppermint oil, purified water, white edible ink

Questions or Comments?

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

PRINCIPAL DISPLAY PANEL

EXTRA STRENGTH GAS RELIEF

ANTIGAS SIMETHICONE 125 mg 30 SOFTGELS

NDC 51013-132-10

*Compare to the active ingredient in Gas-X® Extra Strength Softgels

GAS RELIEF

simethicone capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51013-132
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	125 mg

Inactive Ingredients	
Ingredient Name	**Strength**
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	green (opaque)	**Score**	no score
Shape	capsule (oval)	**Size**	10mm
Flavor		**Imprint Code**	PC2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51013-132-10	3 in 1 CARTON	07/26/2016	
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	07/26/2016	

Labeler - PuraCap Pharmaceutical LLC (962106329)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(51013-132) , analysis(51013-132)

Revised: 7/2016 PuraCap Pharmaceutical LLC