# 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.

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#### Ultra Strength Gas Relief

**Drug Facts** 

Active ingredient (in each softgel)

Simethicone 180 mg

#### Purpose

Antigas

#### Uses

for the relief of

• pressure and bloating 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 2 softgels in 24 hours 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

### **Inactive ingredients**

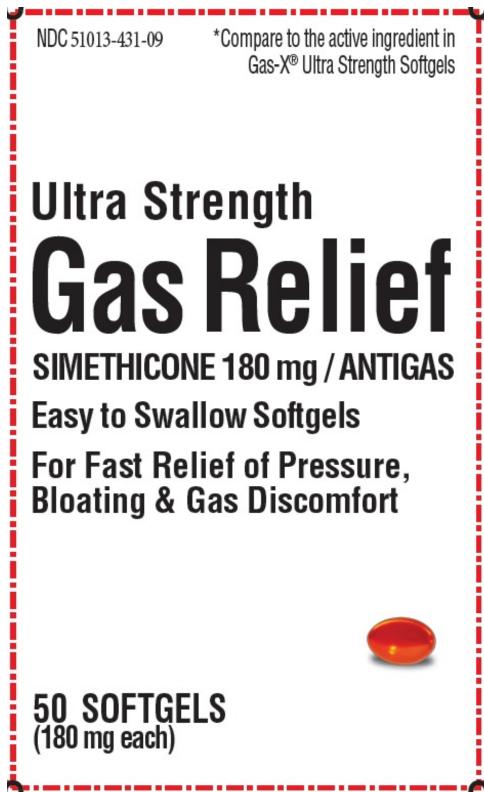
FD&C yellow#6, gelatin, glycerin, purified water and white ink

### Questions or comments?

Call: 1-855-215-8180

### PRINCIPAL DISPLAY PANEL

Ultra Strength Gas Relief Simethicone 180 mg Antigas 50 Softgels NDC 51013-431-09 \*Compare to the active ingredient in Gas-X® Ultra Strength



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Temper evident: Do not use if blister unit is damaged or if printed seal on blister is broken or missing						
Drug Facts	Drug Facts					
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<i>Use</i> for the relief of ■ pressure and bloating commonly referred to as gas						
<i>Warnings</i> Keep out of react	ı of children.					
<ul> <li>Directions</li> <li>■ adults: swallow with water 1 or 2 softgels as needed after meals and at bedtime</li> <li>■ do not exceed 2 softgels in 24 hours except under the advice and supervision of a physician</li> </ul>						
Other information ■ store at controlled room temperature 15°-30°C (59°-86°F) ■ protect from heat and moisture						
FD&C yellow #6, (		fied water, and white ink				
Question or u Call toll free: 1-xx	;omments? x-xxx-xxxx					
*This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, owner of the registered trademark Gas-X® Ultra Strength Softgels.						
Distributed by: PuraCap Pharn 20 Kingsbridge Piscataway, NJ	Road					
Made in China CMB67-00		00000000	000			

## ULTRA STRENGTH GAS RELIEF

simethicone capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51013-431
Route of Administration	ORAL		

A stine Terror discus/A stine Dfairst							
Active Ingredient/Active Moiety Ingredient Name Basis of S	tuonath	Strongth					
Ingredient NameBasis of SDIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10)DIMETHICONE	-	Strength 180 mg					
	5	100 llig					
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	e Marketi	ng End Date					
1         NDC:51013-431-09         5 in 1 CARTON         03/27/2018							
1 10 in 1 BLISTER PACK; Type 0: Not a Combination Product							
Marketing Information							
Marketing Category Application Number or Monograph Citation Marketing Start Date	Marketi	ng 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(51013-431) , analysis(51013-431)			

Revised: 3/2018

#### PURACAP PHARMACEUTICAL LLC