

**ULTRA STRENGTH GAS RELIEF- simethicone capsule, liquid filled
CVS PHARMACY, INC.**

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

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 69842-166-09

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

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<p>ULTRA STRENGTH Gas Relief</p> <table border="1"> <tr> <th colspan="2">Drug Facts</th> </tr> <tr> <td>Active ingredient (in each softgel)</td> <td>Purpose</td> </tr> <tr> <td>Simethicone 180 mg</td> <td>Antigas</td> </tr> <tr> <td colspan="2">Use</td> </tr> <tr> <td colspan="2">for the relief of</td> </tr> <tr> <td colspan="2">■ pressure and bloating commonly referred to as gas</td> </tr> <tr> <td colspan="2">Warnings</td> </tr> <tr> <td colspan="2">Keep out of reach of children.</td> </tr> <tr> <td colspan="2">Directions</td> </tr> <tr> <td colspan="2">■ adults: swallow with water 1 or 2 softgels as needed after meals and at bedtime</td> </tr> <tr> <td colspan="2">■ do not exceed 2 softgels in 24 hours except under the advice and supervision of a physician</td> </tr> <tr> <td colspan="2">Other information</td> </tr> <tr> <td colspan="2">■ store at controlled room temperature 15°-30°C (59°-86°F)</td> </tr> <tr> <td colspan="2">■ protect from heat and moisture</td> </tr> <tr> <td colspan="2">Inactive ingredients</td> </tr> <tr> <td colspan="2">FD&C yellow #6, gelatin, glycerin, purified water, and white ink</td> </tr> <tr> <td colspan="2">Question or comments?</td> </tr> <tr> <td colspan="2">Call toll free: 1-855-215-8180</td> </tr> </table> <p>Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895 © 2018 CVS/pharmacy CVS.com® 1-800-SHOP CVS Made in China V-31141</p> <p> Money Back Guarantee</p> <p><small>*This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, owner of the registered trademark Gas-X® Ultra Strength Softgels.</small></p> <p>CVS46-00</p>	Drug Facts		Active ingredient (in each softgel)	Purpose	Simethicone 180 mg	Antigas	Use		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		Question or comments?		Call toll free: 1-855-215-8180		<p>ULTRA STRENGTH Gas Relief</p> <p>SIMETHICONE 180 mg Anti-gas</p> <p>Fast relief of:</p> <ul style="list-style-type: none"> • Bloating • Pressure • Fullness • Gas <p>#920159</p>  <p>0 50428 36557 1</p>	<p>ULTRA STRENGTH Gas Relief</p> <p>SIMETHICONE 180 mg Anti-gas</p> <p>Fast relief of:</p> <ul style="list-style-type: none"> • Bloating • Pressure • Fullness • Gas <p>Easy to swallow softgels</p>  <p> Actual Size</p> <p>50 SOFTGELS</p>
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ULTRA STRENGTH GAS RELIEF

simethicone capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-166
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: 059QF0K00R)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-166-09	5 in 1 CARTON	02/08/2018	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part332	02/08/2018	

Labeler - CVS PHARMACY, INC. (062312574)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(69842-166) , analysis(69842-166)

Revised: 6/2018

CVS PHARMACY, INC.