

**GAS RELIEF EXTRA STRENGTH- simethicone capsule, liquid filled
P & L Development, 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.

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

If pregnant or breast-feeding,

ask a health professional before use.

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 unless directed by a doctor

Other information

- store between 15-30°C (59-86°F)
- do not refrigerate
- protect from light, heat, and moisture

Inactive ingredients

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

*contains one or more of these ingredients

Questions or comments?

Call **1-877-753-3935 Monday-Friday 9AM-5PM EST**

Principal Display Panel

extra strength

gas relief

simethicone 125 mg

anti-gas

fast relief of

- Pressure
- bloating
- discomfort

softgels

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

†This product is not manufactured or distributed by GSK Consumer Healthcare, distributor of Gas-X® Extra Strength.

TAMPER EVIDENT: DO NOT USE IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Distributed by: **PL Developments**

200 Hicks Street, Westbury, NY 11590

Product Label

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 If pregnant or breast-feeding, ask a health professional before use. 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 unless directed by a doctor	
Other information ■ store between 15-30°C (59-86°F) ■ do not refrigerate ■ protect from light, heat, and moisture	
Inactive ingredients D&C yellow #10, edible ink, FD&C blue #1, FD&C red #40, gelatin, glycerin, peppermint oil, purified water*, sorbitan*, sorbitol*, titanium dioxide *contains one or more of these ingredients	
Questions or comments? Call 1-877-753-3935 Monday-Friday 9AM-5PM EST	

*This product is not manufactured or distributed by GSK Consumer Healthcare, distributor of Gas-X® Extra Strength.

Distributed by: **PL Developments**
200 Hicks Street, Westbury, NY 11590

PLD-A47J
FC004682



extra strength
gas relief



extra strength
gas relief

simethicone 125 mg
antigas

fast relief of

- pressure
- bloating
- discomfort

30 softgels

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

TAMPER EVIDENT: DO NOT USE IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Lot No.:

Exp. Date:

WELLNESS BASICS Extra Strength Gas Relief

GAS RELIEF EXTRA STRENGTH

simethicone capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59726-087
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)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	green	Score	no score
Shape	OVAL	Size	9mm
Flavor		Imprint Code	PO;SCU;L125
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59726-087-30	30 in 1 CARTON	01/31/2018	04/26/2024
1		1 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	part347	01/31/2018	04/26/2024

Labeler - P & L Development, LLC (800014821)

Revised: 10/2021

P & L Development, LLC