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

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 except under the advice and supervision of a physican

Other information

- store between 20-25°C (68-77°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, mannitol, peppermint oil, purified water, sorbitan, sorbitol, titanium dioxide

Questions or comments?

Principal Display Panel

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

extra strength

gas relief

simethicone 125 mg

anti-gas

Relieves:

- Pressure
- bloating
- discomfort

softgels

†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.

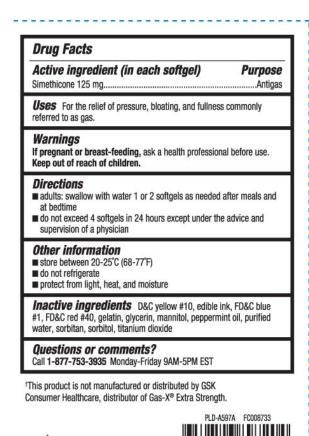
Distributed by:

PL Developments

200 Hicks Street

Westbury, NY 11590

Product Label





extra strength

Gas relief

simethicone 125 mg



KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

READYinCASE Extra Strength Gas Relief

Lot No.: Exp. Date:

GAS RELIEF EXTRA STRENGTH

simethicone capsule, liquid filled

Product Information

Distributed by:

PL Developments

Westbury, NY 11590

200 Hicks Street

Product Type HUMAN OTC DRUG Item Code (Source) NDC:59726-897

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (LINII: 92RI3N3Y1O) (DIMETHICONE - LINII: 92RI3N3Y1O)	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: 6092ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MANNITOL (UNII: 30WL53L36A)	

Product Characteristics			
Color	green	Score	no score
Shape	OVAL	Size	9mm
Flavor		Imprint Code	PO
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:59726- 897-10	10 in 1 CARTON	07/31/2019		
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product			
2	NDC:59726- 897-51	150 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/31/2019		
3	NDC:59726- 897-15	15 in 1 CARTON	07/31/2019		
3		1 in 1 BLISTER PACK; Type 0: Not a Combination Product			
4	NDC:59726- 897-50	50 in 1 CARTON	07/31/2019		
4		1 in 1 BLISTER PACK; Type 0: Not a Combination Product			
5	NDC:59726- 897-30	30 in 1 CARTON	07/31/2019		
5		1 in 1 BLISTER PACK; Type 0: Not a Combination Product			
6	NDC:59726- 897-20	20 in 1 CARTON	07/31/2019		
6		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 Drug	M016	07/31/2019	

Labeler - P & L Development, LLC (800014821)

Revised: 4/2024 P & L Development, LLC