

ULTRA STRENGTH GAS RELIEF- 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 180 mg

Purpose

Antiflatulent (Antigas)

Uses

- relieves bloating, pressure, or fullness commonly referred to as gas

Warnings

Stop use and ask a doctor if

condition persists.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

Directions

- swallow one or two softgels as needed after a meal
- do not exceed two softgels per day except under the advice and supervision of a physician

Other information

- store at 15°-30°C (59°-86°F)

Inactive ingredients

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

Questions or comments?

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

Principal Display Panel

Compare to the active ingredient in **Phazyme® Ultra Strength†**

Ultra Strength

Gas Relief

Simethicone 180 mg

Anti-gas

Fast Relief of:

• Pressure • Bloating • Discomfort

Softgels

Small, easy to swallow

†This product is not manufactured or distributed by C.B. Fleet Company Inc., distributor of Phazyme®.

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR 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

Package Label

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



PLD-C
FC002008



Compare to the active ingredient in
Phazyme® Ultra Strength[†]

NDC 59726-530-10

ultra strength
gas relief
simethicone 180 mg

ultra strength
gas relief
simethicone 180 mg

anti-gas

fast relief of:

- pressure
- bloating
- discomfort

small, easy
to swallow



10 softgels

Lot No.:
Exp. Date:

ReadyInCase Ultra Strength Gas Relief Softgel

ULTRA STRENGTH GAS RELIEF

simethicone capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59726-530
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
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SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	orange (ORANGE)	Score	no score
Shape	OVAL (OVAL)	Size	11mm
Flavor		Imprint Code	S180
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59726-530-10	1 in 1 BOX	09/01/2011	09/01/2024
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	09/01/2011	09/01/2024

Labeler - P & L Development, LLC (800014821)

Revised: 4/2023

P & L Development, LLC