

**SIMETHICONE 250MG- simethicone 250mg capsule, liquid filled
AMZ789 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.

Simethicone 250mg

Simethicone 180mg

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

stop use and ask a doctor if condition persists

if pregnant or breast-feedingm ask a health professional before use

Keep out of reach of children

- 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

Uses relieves ■ bloating ■ pressure ■ fullness commonly referred to as gas

FD&C Blue #1, FD&C Red #40, gelatin, glycerin, purified water, and white edible ink



Drug Facts	Active ingredient (in each softgel) Simethicone 250mg.....Antiflatulent (Antigas)	Purpose Antiflatulent (Antigas)
	Uses relieves ●bloating ●pressure ●fullness ●discomfort ●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 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 between 59-86°F (15-30°C)	
	Inactive ingredients FD&C rec#33, FD&C blue#1, gelatin, glycerin, purified water, sorbitol, and white edible ink	

*This product is not affiliated with the owner of the trademark Ultra Strength Phazyme.
Distributed by: AMZ789 LLC, Smithtown, NY 11787
LB1006 Rev1231

SIMETHICONE 250MG			
simethicone 250mg capsule, liquid filled			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73629-006
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)		DIMETHICONE	250 mg	
Inactive Ingredients				
Ingredient Name		Strength		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
GELATIN (UNII: 2G86QN327L)				
GLYCERIN (UNII: PDC6A3C0OX)				
WATER (UNII: 059QF0KO0R)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
Product Characteristics				
Color	purple	Score	no score	
Shape	OVAL	Size	13mm	
Flavor		Imprint Code	PC31	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73629-006-12	120 in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2022	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	M002	12/01/2022		

Labeler - AMZ789 LLC (117410213)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell Puracap Pharmaceuticals (Wuhan) Co., Ltd		421293287	manufacture(73629-006)

Revised: 5/2023

AMZ789 LLC