PHAZYME ULTIMATE- simethicone capsule, liquid filled C.B. Fleet Company, 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.

Phazyme Ultimate 500 mg

Drug Facts

Active ingredient (in each fast gel)

Simethicone 500mg

Purpose

Anti-gas

Use

Relieves bloating, pressure, or fullness commonly referred to as gas

Warnings

Stop use and ask a doctor if

condition persists.

Keep out of reach of children.

Directions

- Swallow (1) Fast Gel as symptoms occur
- Do not exceed (1) Fast Gel per 24 hours except under the advice and supervision of a physician

Other information

Store at room temperature 59°- 86°F (15°-30°C).

Inactive ingredients

FD&C Blue #1, gelatin, glycerin, water

Questions?

Call toll-free 1-855-727-4277

TAMPER EVIDENT PACKAGE

Do not use if blister or printed foil is broken or torn, or if "PZ500" is missing from Fast Gel.

Principal Display Panel

PHAZYME® ULTIMATE

ANTI-GAS SIMETHICONE 500 mg

10 fast gels



PHAZYME ULTIMATE

simethicone capsule, liquid fil	led				
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (So	ource)	NDC:013	32-0217
Route of Administration	ORAL				
Active Ingredient/Active	Moiety				
Ingredient Name Basis of Strength Strength				Strength	
DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RI	J3N3Y1O)	DIMETHICONE		500 mg

Inactive Ingredients			
Ingredient Name	Strength		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
WATER (UNII: 059QF0KO0R)			
GELATIN (UNII: 2G86QN327L)			
GLYCERIN (UNII: PDC6A3C0OX)			

Product Characteristics				
Color	blue	Score	no score	
Shape	CAPSULE	Size	11mm	
Flavor		Imprint Code	PZ 500	
Contains				

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:0132- 0217-10	1 in 1 BOX	02/15/2021		
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product			
2	NDC:0132- 0217-20	2 in 1 BOX	02/15/2021		
2		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	02/15/2021		

Labeler - C.B. Fleet Company, Inc. (003119054)

Revised: 12/2022 C.B. Fleet Company, Inc.