

PHAZYME- simethicone capsule, gelatin coated
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.

Drug Facts

Active Ingredient

(in each softgel)

Simethicone 250mg

Purpose

Anti-gas

Use

relieves bloating, pressure or fullness commonly referred to as gas

Warnings

Stop use and ask a doctor if

Stop use and ask a doctor if condition persists

Keep out of reach of children.

Directions

- swallow one or two softgels after a meal
- do not exceed two softgels 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

Red No. 33, FD&C Blue No. 1, Purified Water, Gelatin, Glycerin, Titanium Dioxide

Questions?

Call toll-free 1-855-727-4277

PHAZYME

simethicone capsule, gelatin coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0132-0214
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
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
WATER (UNII: 059QF0KO0R)	
GELATIN (UNII: 2G86QN327L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	purple	Score	no score
Shape	CAPSULE	Size	11mm
Flavor		Imprint Code	PZ;250
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0132-0214-24	1 in 1 BOX	04/01/2014	
1		24 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	04/01/2014	

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

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