

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.

Phazyme Ultra Strength 180 mg 0132-0208

Drug Facts

Active Ingredient (in each fast gel)

Simethicone 180mg

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 one or two fast gels as symptoms occur
- Do not exceed two fast gels 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 red no. 40, FD&C yellow no. 6, gelatin, glycerin, purified 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 "PZ180" is missing from Fast Gel.

Principal Display Panel

PHAZYME® ULTRA STRENGTH
 ANTI-GAS SIMETHICONE 180 MG
 12 fast gels



PHAZYME

simethicone capsule, gelatin coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0132-0208
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
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	

WATER (UNII: 059QF0KO0R)

Product Characteristics

Color	ORANGE	Score	no score
Shape	CAPSULE	Size	11mm
Flavor		Imprint Code	PZ;180
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0132-0208-12	1 in 1 BOX	02/01/2012	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0132-0208-48	1 in 1 BOX	02/01/2012	
2		48 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	02/01/2012	

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

Revised: 12/2020

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