# 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.

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## Phazyme Maximum Strength 250 mg 0132 - 0211

## **Drug Facts**

### **Active Ingredient (in each fast gel)**

Simethicone 250 mg

## **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**

DC Red #33, FD&C Blue #1, gelatin, glycerin, purified water

#### Questions?

Call toll-free 1-855-727-4277

## **Principal Display Panel**

**PHAZYME®** 

ANTI-GAS SIMETHICONE 250 mg

MAXIMUM STRENGTH

12 fast gels



#### **PHAZYME**

simethicone capsule, gelatin coated

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:0132-0211

Route of Administration ORAL

## **Active Ingredient/Active Moiety**

Ingredient Name	<b>Basis of Strength</b>	Strength
DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10)	DIMETHICONE	250 mg

Inactive Ingredients				
Ingredient Name	Strength			
D&C RED NO. 33 (UNII: 9DBA0SBB0L)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
GELATIN (UNII: 2G86QN327L)				
GLYCERIN (UNII: PDC6A3C0OX)				
WATER (UNII: 059QF0KO0R)				

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- 0211-12	1 in 1 BOX	04/01/2014		
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product			
2	NDC:0132- 0211-24	2 in 1 BOX	04/01/2014		
2		12 in 1 BLISTER PACK; Type 0: Not a Combination Product			
3	NDC:0132- 0211-36	3 in 1 BOX	04/01/2014		
3		12 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)

Revised: 5/2023 C.B. Fleet Company, Inc.