SIMETHICONE- simethicone capsule, liquid filled PURACAP PHARMACEUTICAL 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.

MAXIMUM STRENGTH GAS RELIEF

Active ingredient

Simethicone 250 mg

Purpose

Anti-gas

Uses

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 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)

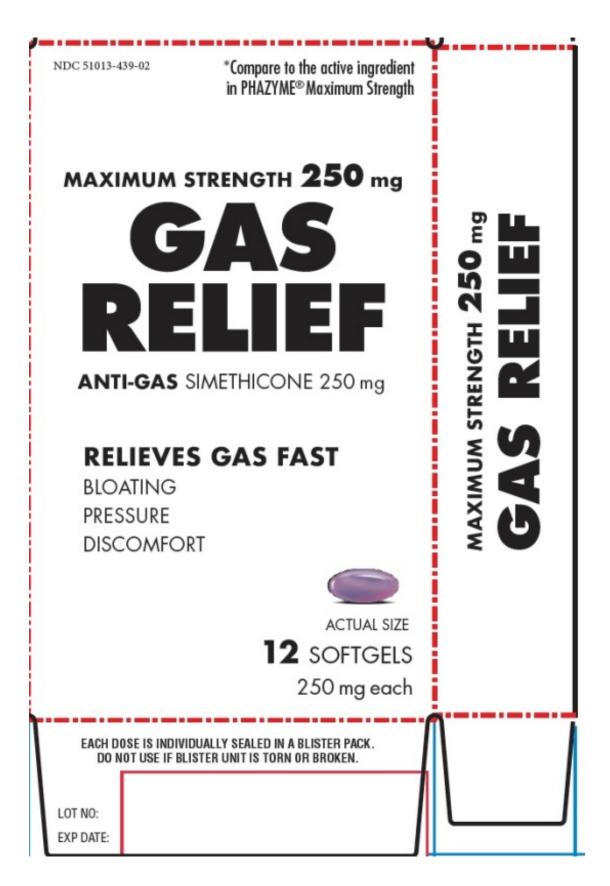
Inactive Ingredients

D&C red # 33, FD&C blue # 1, gelatin, glycerin, purified water and white edible ink

Questions or comments?

Call toll free: 1-855-215-8180

Package/Label Principal Display Panel - Principal Display Panel



Package/Label Principal Display Panel – Drug Facts

Drug Facts

Active ingredient (in each softgel) Simethicone 250 mg......Anti-gas

Purpose

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 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 D&C red #33, FD&C blue #1, gelatin, glycerin, purified water and white edible ink

Questions or comments? Call toll free: 1-855-215-8180

This product is not manufactured or distributed by C.B. Fleet Company Inc., distributor of PHAZYME®.

> Distributed By: COMPANY NAME ADDRESS Made in China



WG11-00

SIMETHICONE

simethicone capsule, liquid filled

Product Information	Prod	nct	Info	rmat	ion
---------------------	------	-----	------	------	-----

Product Type HUMAN OTC DRUG Item Code (Source) NDC:51013-439

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)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)			
GLYCERIN (UNII: PDC6A3C0OX)			
WATER (UNII: 059QF0KO0R)			

Product Characteristics				
Color	PURPLE (Clear)	Score	no score	
Shape	CAPSULE (Oval)	Size	13mm	
Flavor		Imprint Code	PC31	
Contains				

ı	Packaging				
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
l	1 NDC:51013-439-02	1 in 1 CARTON	03/25/2019		
l	1	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	03/25/2019		

Labeler - PURACAP PHARMACEUT ICAL LLC (962106329)

Revised: 3/2019 PURACAP PHARMACEUTICAL LLC