

MAXIMUM STRENGTH GAS RELIEF- 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 (in each softgel)

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 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**

PRINCIPAL DISPLAY PANEL

MB MAXIMUM STRENGTH Gas Relief

SIMETHICONE 250 mg 24 SOFTGELS

NDC 51013-177-04

Compare to PHAZYME® Maximum Strength active ingredient*



MAXIMUM STRENGTH GAS RELIEF

simethicone capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51013-177
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: HBR47K3TBD)	

GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color	purple (clear)	Score	no score
Shape	capsule (oval)	Size	13mm
Flavor		Imprint Code	PC31
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:510 13-177-04	2 in 1 CARTON	07/28/2016	
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	07/28/2016	

Labeler - PuraCap Pharmaceutical LLC (962106329)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(510 13-177) , analysis(510 13-177)