SIMETHICONE 250MG- simethicone 250mg capsule, liquid filled
AMZ789 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.

Simethicone 250mg

Simethicone 180mg

relieves bloating, pressure, fullness, commonly referred to as gas

stop use and ask a doctor if condition persists

if pregnant or breast-feedingm ask a health professional before use

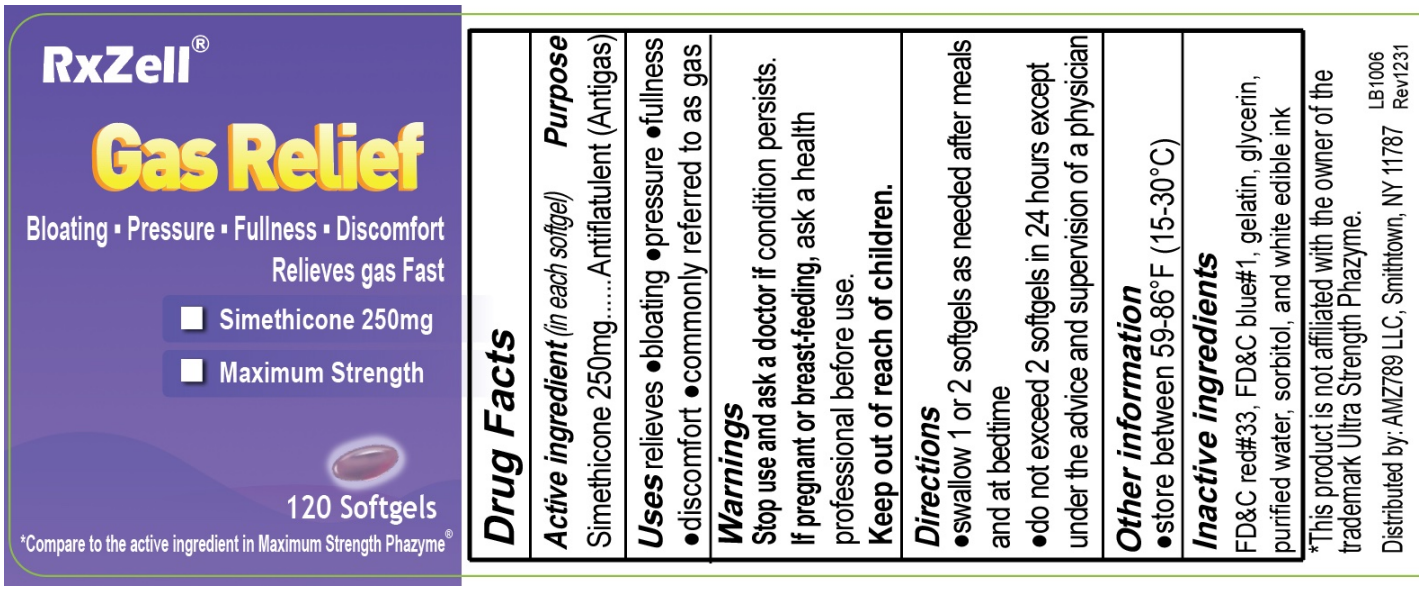
Keep out of reach of children

■ swallow one or two softgels as needed after a meal

■ do not exceed two softgels per day except under the advice and supervision of a physician

Uses relieves ■ bloating ■ pressure ■ fullness commonly referred to as gas

FD&C Blue #1, FD&C Red #40, gelatin, glycerin, purified water, and white edible ink



SIMETHICONE 250MG

simethicone 250mg capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73629-006
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
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Product Characteristics

Color	purple	**Score**	no score
Shape	OVAL	**Size**	13mm
Flavor		**Imprint Code**	PC31
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73629-006-12	120 in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M002	12/01/2022	

Labeler - AMZ789 LLC (117410213)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell Puracap Pharmaceuticals (Wuhan) Co., Ltd		421293287	manufacture(73629-006)

Revised: 5/2023 AMZ789 LLC