SIMETHICONE- simethicone 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 180mg

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

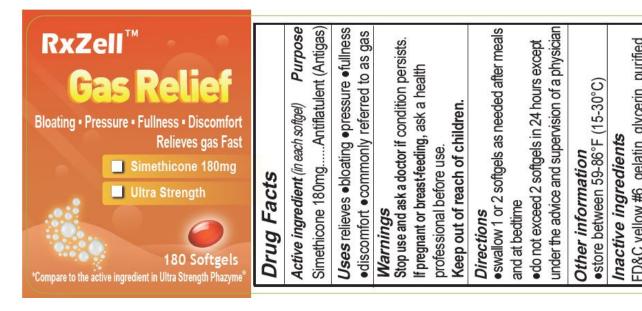
Uses relieves ■ bloating ■ pressure ■ fullness commonly referred to as gas

FD&C yellow #6, gelatin, glycerin, purified water, sorbitol

RxZell

Fast Acting Gas Relief

Package Label Principle Display Panel



SIMETHICONE

simethicone capsule, liquid filled

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:73629-002 Route of Administration ORAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10)	DIMETHICONE	180 mg		

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
GLYCERIN (UNII: PDC6A3C0OX)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
GELATIN (UNII: 2G86QN327L)			

Product Characteristics				
Color	orange	Score	no score	
Shape	OVAL	Size	13mm	
Flavor		Imprint Code	PC3	
Contains				

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:73629-002- 18	180 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part332	05/01/2021	

Labeler - AMZ789 LLC (117410213)

Establishment				
Name	Address	ID/FEI	Business Operations	
Humanwell Puracap Pharmaceuticals (Wuhan) Co., Ltd		421293287	manufacture(73629-002)	

Revised: 5/2023 AMZ 789 LLC