

**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-feeding 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**



<b>Drug Facts</b>	<b>Purpose</b> Simethicone 180mg.....Antiflatulent (Antigas)
<b>Active ingredient (in each softgel)</b> Simethicone 180mg.....Antiflatulent (Antigas)	<b>Uses</b> relieves ●bloating ●pressure ●fullness ●discomfort ●commonly referred to as gas
<b>Warnings</b> Stop use and ask a doctor if condition persists. If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.	
<b>Directions</b> ●swallow 1 or 2 softgels as needed after meals and at bedtime ●do not exceed 2 softgels in 24 hours except under the advice and supervision of a physician	
<b>Other information</b> ●store between 59-86°F (15-30°C)	
<b>Inactive ingredients</b> FD&C yellow #6, gelatin, glycerin, purified water, sorbitol	

\*This product is not affiliated with the owner of the trademark Ultra Strength Phazyme.  
Distributed by: AMZ789 LLC, Smithtown, NY 11787  
LB1002 Rev0401

**SIMETHICONE**

simethicone capsule, liquid filled

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73629-002
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	180 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GELATIN</b> (UNII: 2G86QN327L)	

**Product Characteristics**

<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	13mm
<b>Flavor</b>		<b>Imprint Code</b>	PC3
<b>Contains</b>			

**Packaging**

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

**Marketing Information**

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

**Labeler** - AMZ789 LLC (117410213)**Establishment**

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