

**SIMETHICONE- simethicone capsule, liquid filled  
ONE2ZEE LIMITED LIABILITY COMPANY**

*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.*

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**SIMETHICONE CAPSULES 250 mg, liquid filled**

**Active ingredient (in each capsule)**

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**

gelatin, glycerin, sorbitol, fd&c blue no. 1, fd&c red no. 40, povidone k30, titanium dioxide, water

**PRINCIPAL DISPLAY PANEL - Shipping Label**

Simethicone capsules

Each Softgel Contains:  
(Simethicone 250mg)

LOT NO:  
DRUM NO:  
MFG DATE:  
QUANTITY:  
NDC NO: 55629-017-  
EXP DATE:

WARNING:  
KEEP OUT OF REACH OF CHILDREN

STORE CONTROLLED ROOM TEMPERATURE OF 59° - 86°F (15° - 30°C)  
PROTECT FROM LIGHT, MOISTURE AND FREEZING

THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY.

CONTENTS SHOULD BE APPROVED, REPACKAGED IMMEDIATELY AND LABELED IN STRICT CONFORMANCE WITH THE F.D & C.ACT AND REGULATIONS THEREUNDER.

Simethicone ..... 250 mg soft gelatin capsule			
Each soft gelatin capsule Contains:- Simethicone USP.....250 mg			
BATCHNO.		QUANTITY	48X1500 softgels
MFG.DATE		SHIPPER NO.	
EXP.DATE		GROSS WT.	
NDC NO.	xxxxxxx		
<b>WARNING:</b> KEEP OUT OF THE REACH OF CHILDREN		STORE AT CONTROLLED TEMPERATURE OF 59°F to 86°F (15°C to 30°C)	
THIS IS BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY CONTENTS SHOULD BE APPROVED, REPACKAGED IMMEDIATELY AND LABELED IN STRICT CONFORMANCE WITH THE F.D & C. ACT AND REGULATIONS THEREUNDER.		PROTECT FROM DIRECT SUNLIGHT / MOISTURE / FREEZING	
MANUFACTURED BY: MEDGEL PRIVATE LIMITED Plot No. 19-20, Special Economic Zone-II (Pharma Zone), Sector-III, Pithampur, Distt. Dhar-454775, Madhya Pradesh, India.		MANUFACTURED FOR:  xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	
LABELLER CODE : xxxx		LABELLER CODE : xxxx	
MFG. LIC. NO. : xxxxxxxxxxxxxxxxxxxxxx			
CAUTION: "FOR MANUFACTURING, PROCESSING OR REPACKING"			

## SIMETHICONE

simethicone capsule, liquid filled

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55629-017
<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	250 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	
<b>Povidone K30</b> (UNII: U725QWY32X)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Product Characteristics

<b>Color</b>	purple	<b>Score</b>	no score
<b>Shape</b>	capsule	<b>Size</b>	13mm
<b>Flavor</b>		<b>Imprint Code</b>	IS9
<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:55629-017-01	48 in 1 CARTON	03/02/2021	
1	NDC:55629-017-02	1500 in 1 POUCH; Type 0: Not a Combination Product		

## 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	03/02/2021	

**Labeler** - ONE2ZEE LIMITED LIABILITY COMPANY (078656111)

**Registrant** - ONE2ZEE LIMITED LIABILITY COMPANY (078656111)

## Establishment

Name	Address	ID/FEI	Business Operations
Medgel Private Limited		677385498	manufacture(55629-017)

Revised: 3/2023

ONE2ZEE LIMITED LIABILITY COMPANY