

**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.

Extra Strength Gas Relief

Active ingredient (in each softgel)

Simethicone 125mg

Purpose

Antigas

Use

for the relief of

- pressure, bloating, and fullness commonly referred to as gas

Warning

Keep out of reach of children.

Directions

- adults: swallow with water 1 or 2 softgels as needed after meals and at bedtime
- do not exceed 4 softgels in 24 hours except under the advice and supervision of a physician

Other Information

- store at controlled room temperature 20-25°C (68-77°F)
- protect from light, heat, and moisture

Inactive ingredients

FD&C blue 1, FD&C yello#10, gelatin, glycerin, peppermint oil, purified water, sorbitol sorbitan, titanium dioxide

PRINCIPAL DISPLAY PANEL - Shipping Label

IMETHICONE CAPSULES, 325 mg

Quantity : 48 Bags of 1500 Capsules each
 NDC. No : 55629-010-01

Important:

1. Inspect immediately upon receipt
2. This is bulk shipment intended for further processing only
3. store at controlled room temperature 20-25°C (68-77°F), protect from light, heat, and moisture

Simethicone 125 mg Soft Gelatin Capsule			
Each soft gelatin capsule Contains: Simethicone..... 125 mg & ExcipientsQS.			
BATCH NO.	M21ZH001	QUANTITY	48X1500 softgels
MFG.DATE		SHIPPER NO.	
EXP.DATE		GROSS WT.	
NDC NO.			
WARNING: KEEP OUT OF THE REACH OF CHILDREN		STORE AT CONTROLLED TEMPERATURE OF 59°F to 86°F (15°C to 30°C) AVOID HIGH HUMIDITY AND EXCESSIVE HEAT ABOVE 104°F(40°C)	
MADE IN INDIA INSPECT IMMEDIATELY UPON RECEIPT. THIS IS BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY. PRODUCT TO BE PRIMARY PACKED IN BLISTER AND BOTTLE PACK. PRODUCT BEST IN POUCH FOR 06 MONTH FROM THE DATE OF MAUFACTURING.		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: One2Zee, LLC 61 Bay Hill Blvd, Monroe Township, NJ 08831, USA	
LABELLER CODE	: 51344	LABELLER CODE	: 55629
MFG. LIC. NO.	: MP/DRUGS/25/4/2011		
CAUTION: "FOR REPACKING ONLY"			

SIMETHICONE

simethicone capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55629-010
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	125 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
Povidone K30 (UNII: U725QWY32X)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	green	Score	no score
Shape	OVAL	Size	8mm
Flavor		Imprint Code	YH3
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55629-010-01	48 in 1 CARTON	01/19/2021	
1	NDC:55629-010-02	1500 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	01/19/2021	

Labeler - ONE2ZEE LIMITED LIABILITY COMPANY (078656111)

Registrant - ONE2ZEE LIMITED LIABILITY COMPANY (078656111)

Establishment

Name	Address	ID/FEI	Business Operations
Medgel Private Limited		677385498	manufacture(55629-010)