# SIMETHICONE- simethicone capsule, liquid filled Softgel Healthcare Pvt Ltd

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### Simethicone Capsules USP, 180 mg

### Active ingredient (in each softgel)

Simethicone USP 180 mg

### **Purpose**

**Antigas** 

#### Use

for the relief of

pressure, bloating, and fullness commonly referred to as gas

### Warnings

### 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 2 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 moisture
- read all product information before using.
- Keep this box for important information

### Inactive ingredients

FD&C yellow no.6, gelatin, glycerin, peppermint oil, purified water, sorbitol, titanium dioxide

### **Principal Display Panel**

NDC 35916-1939-2

Compare to Gas-X ® Ultra Strength Active Ingredient\*

Simethicone Capsules USP, 180 mg

Simethicone 180 mg / Antigas

#### **RELIEVES GAS FAST:**

- Pressure
- Bloating
- Discomfort

50 Softgels



### **Bulk Package Label**

### Simethicone Capsules USP, 180 mg

Each Soft Gelatin Capsule Contains: (SimethiconeUSP 180 mg)

Batch No.

Net Wt

Quantity

Gross Wt

NDC No

Mfg Date

: 35916-1939-1

IMPRINT

Exp Date

WARNING KEEP OUT OF REACH OF CHILDREN

STORE AT CONTROLLED ROOM TEMPERATURE 20-25°C (68-77°F) PROTECT FROM MOISTURE

THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY. CONTENTS SHOULD BE APPROVED, REPACKED IMMEDIATELY AND LABELED IN STRICT CONFORMANCE WITHTHE F.D. & C ACT AND REGULATIONS.

MANUFACTURED BY:

MANUFACTURED FOR:

SOFTGEL HEALTHCARE PVT. LTD.,

SURVEY NO. 20/1, VANDALUR - KELAMBAKKAM ROAD,

PUDUPAKKAM VILLAGE, KANCHEEPURAM,

TAMILNADU 603 103, INDIA (IND).

LABELLER CODE: 35916 LIC NO. :XXXX

CAUTION: "FOR MANUFACTURING, PROCESSING OR REPACKAGING"

### **SIMETHICONE**

simethicone capsule, liquid filled

#### **Product Information**

**Product Type** HUMAN OTC DRUG **Item Code (Source)** NDC:35916-1939

**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**

GELATIN (UNII: 2G86QN327L)

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
PEPPERMINT OIL (UNII: AV092KU4JH)	

<b>GLYCERIN</b>	(UNII:	PDC6A3C0OX)
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Product Characteristics				
Color	orange	Score	no score	
Shape	OVAL	Size	11mm	
Flavor		Imprint Code		
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:35916- 1939-1	1000 in 1 BAG; Type 0: Not a Combination Product	04/05/2025		
2	NDC:35916- 1939-2	5 in 1 CARTON	04/05/2025		
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M002	04/05/2025	

## Labeler - Softgel Healthcare Pvt Ltd (675584180)

Revised: 4/2025 Softgel Healthcare Pvt Ltd