

**SIMETHICONE- simethicone capsule, liquid filled
SOFTGEL HEALTHCARE PRIVATE LIMITED**

Simethicone Capsules USP, 250 mg

Active ingredient (in each softgel)

Simethicone USP 250 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 and children 12 years and older: 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 light, heat, and moisture

Inactive ingredients

D&C red no.33, FD&C blue no.1, gelatin, glycerin, purified water

Principal Display Panel

Simethicone Capsules USP, 250 mg		IMPRINT
Each Soft Gelatin Capsule Contains: (Simethicone USP 250 mg)		
Batch No. :	NDC No : 35916-1940-1	
Gross Wt :	Mfg Date :	
Net Wt :	Exp Date :	
Quantity :		
WARNING KEEP OUT OF REACH OF CHILDREN		
STORE AT CONTROLLED ROOM TEMPERATURE 20-25°C (68-77°F) PROTECT FROM LIGHT, HEAT AND MOISTURE		
THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY. CONTENTS SHOULD BE APPROVED, REPACKED IMMEDIATELY AND LABELED IN STRICT CONFORMANCE WITH THE F.D. & C ACT AND REGULATIONS.		
MANUFACTURED BY:		MANUFACTURED FOR:
SOFTGEL HEALTHCARE PVT. LTD., SURVEY NO. 20/1, VANDALUR – KELAMBAKKAM ROAD, PUDUPAKKAM, CHENGALPATTU, TAMILNADU 603 103, INDIA (IND). LABELLER CODE : 35916 LIC NO. :XXXX		
CAUTION: "FOR MANUFACTURING, PROCESSING OR REPACKAGING"		

NDC 35916-1940-2

Compare to Gas-X[®] Maximum Strength Active Ingredient*

Simethicone Capsules USP, 250 mg

Simethicone 250 mg / Antigas (Relieves Gas Fast)

RELIEVES GAS FAST:

- Pressure
- Bloating
- Discomfort

50 Softgels

SIMETHICONE			
simethicone capsule, liquid filled			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35916-1940
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	250 mg

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GELATIN (UNII: 2G86QN327L)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	purple (Transparent)	Score	no score
Shape	OVAL	Size	11mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35916-1940-1	1000 in 1 BAG; Type 0: Not a Combination Product	10/28/2025	
2	NDC:35916-1940-2	5 in 1 CARTON	10/28/2025	
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	10/28/2025	

Labeler - SOFTGEL HEALTHCARE PRIVATE LIMITED (676666501)