

SIMETHICONE- simethicone capsule, liquid filled
Softgel Healthcare Pvt Ltd

Simethicone Capsules USP, 125 mg

Active ingredient (in each softgel)

Simethicone USP 125 mg

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 and children 12 years and older: 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

D&C yellow no.10, FD&C blue no. 1, FD&C red no.40, gelatin, glycerin, peppermint oil, purified water, sorbitol sorbitan solution, titanium dioxide

Principal Display Panel

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

NDC 35916-1938-2

Simethicone Capsules USP, 125 mg

Simethicone 125 mg / Antigas (Relieves Gas Fast)

Pressure, Bloating, Discomfort

30 Softgels

| | | |
|--|--|---|
| Simethicone Capsules USP, 125 mg | | <div style="border: 1px solid black; padding: 5px; width: 100px; margin: 0 auto;">IMPRINT</div> |
| Each Soft Gelatin Capsule Contains: (Simethicone USP 125 mg) | | |
| Batch No. : | | NDC No : 35916-1938-3 |
| 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" | | |

SIMETHICONE

simethicone capsule, liquid filled

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:35916-1938 |
| 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) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| GELATIN (UNII: 2G86QN327L) | |
| PEPPERMINT OIL (UNII: AV092KU4JH) | |

| | |
|---|--|
| SORBITOL (UNII: 506T60A25R) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| WATER (UNII: 059QF0KO0R) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|----------|
| Color | green | Score | no score |
| Shape | OVAL | Size | 11mm |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:35916-1938-1 | 1000 in 1 BAG; Type 0: Not a Combination Product | 10/28/2025 | |
| 2 | NDC:35916-1938-2 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 10/28/2025 | |
| 3 | NDC:35916-1938-3 | 2 in 1 BOX | 01/16/2026 | |
| 3 | | 1500 in 1 BAG; 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 Pvt Ltd (676666501)

Revised: 1/2026

Softgel Healthcare Pvt Ltd