

**SIMETHICONE- simethicone capsule, liquid filled**  
**Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd**

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**Simethicone Capsules 250 mg**

**Drug Facts**

**Active ingredient (in each softgel)**

Simethicone 250 mg

**Purpose**

Anti-gas

**Use**

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**

D&C red # 33, FD&C blue # 1, gelatin, glycerin, purified water and white edible ink

**PRINCIPAL DISPLAY PANEL - Shipping Label**

Simethicone Capsules 250 mg

NDC 53345-032-02

Quantity: 12 Capsules per blister

124 Blisters per box

**IMPORTANT:**

Inspect immediately upon receipt.

This is a bulk shipment, intended for further processing only.

Protect from heat, humidity, and light. Do not refrigerate.

Store at 15-30°C (59-86°F)

**CAUTION : FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING**

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**Humanwell PuraCap Pharmaceutical (Wuhan) Ltd.**

No. 99, 2nd Shendun Road, East Lake New Technology Development District,

Wuhan, Hubei 430206, P. R. China

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**NDC No.: 53345-032-02**

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**Product:**

**Simethicone Capsules 250 mg**

Each softgel contains: Simethicone 250 mg

**CAUTION: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING**

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**Product Code:**

40-00028

**Quantity:**

12 Capsules per blister

124 Blisters per box

**Lot Number:**

XXXXXXXX

**Manufacturing Date:**

MM/YYYY

|                      |   |   |
|----------------------|---|---|
| <b>Box No.:</b>      | <b>IMPORTANT:</b><br>1. Inspect immediately upon receipt.<br>2. This is a bulk shipment, intended for further processing only.<br>3. Protect from heat, humidity, and light. Do not refrigerate.<br>4. Store at 15-30°C (59-86°F) |  |
| <b>MADE IN CHINA</b> |   |   |

REV-00  
05/2016

## SIMETHICONE

simethicone capsule, liquid filled

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:53345-032 |
| <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

| Ingredient Name                               | Strength |
|---|----------|
| <b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)  |          |
| <b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD) |          |
| <b>GELATIN</b> (UNII: 2G86QN327L)             |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)            |          |
| <b>WATER</b> (UNII: 059QF0KO0R)               |          |

## Product Characteristics

|                 |                |                     |          |
|-----------------|----------------|---------------------|----------|
| <b>Color</b>    | purple (clear) | <b>Score</b>        | no score |
| <b>Shape</b>    | CAPSULE (oval) | <b>Size</b>         | 13mm     |
| <b>Flavor</b>   |                | <b>Imprint Code</b> | PC31     |
| <b>Contains</b> |                |                     |          |

## Packaging

| # | Item Code        | Package Description                                     | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:53345-032-02 | 124 in 1 BOX  | 06/30/2016           |                    |
| 1 |                  | 12 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                                     | 06/30/2016           |                    |

**Labeler** - Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd (421293287)

## Establishment

| Name  | Address | ID/FEI    | Business Operations    |
|---|---------|-----------|------------------------|
| Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd |         | 421293287 | manufacture(53345-032) |

Revised: 11/2024

Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd