

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

-----

**Active ingredient (in each capsule)**

Simethicone 125 mg

**Purpose**

Antiflatulent

***Uses for relief of:***

- bloating
- pressure
- fullness
- stuffed feeling commonly referred to as gas

**Warnings**

**Stop use and ask a doctor** if condition persists.

**If pregnant or breast-feeding**, ask a health care professional before use.

**Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

- **adults:** swallow with water 1 or 2 softgels as needed after meals or at bedtime
- do not exceed 4 softgels per day unless directed by doctor

**Other information**

- store at controlled room temperature 15°-30°C (59°-86°F)
- protect from heat and moisture
- do not use if imprinted safety seal under cap is broken or missing

**Inactive ingredients**

D&C Yellow #10, FD&C Blue #1, FD&C Red #40, gelatin, glycerin, peppermint oil, purified water, titanium dioxide and white edible ink

Manufactured by:  
Humanwell PuraCap Pharmaceutical (Wuhan) Ltd.

Wuhan, Hubei  
430206, China

**PRINCIPAL DISPLAY PANEL - Shipping Label**

SIMETHICONE CAPSULES, 125 mg

Quantity : 25000 Capsules

NDC. No : 53345-009-01

IMPORTANT:

Inspect immediate upon receipt.

This is a bulk shipment intended for further processing only.

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

CAUTION : "FOR FURTHER MANUFACTURING, PROCESSING OR REPACKING"

---

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

No. 99, 2<sup>nd</sup> Shendun Road, East Lake New Technology Development District,  
Wuhan, Hubei 430206, P. R. China

---

NDC No.: 53345-009-01

---

Product:

**SIMETHICONE CAPSULES, 125 mg**

Each softgel contains: Simethicone USP, 125 mg

CAUTION: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING

Product Code: <b>40-00002</b>	Quantity: <b>25000 Capsules</b>
Lot No.: <b>0000000</b>	Manufacturing Date: <b>00/0000</b>
Box No.: <b>X</b>	<b>IMPORTANT:</b> 1. Inspect immediately upon receipt. 2. This is a bulk shipment intended for further processing only. 3. Protect from heat, humidity, and light. Do not refrigerate.
<b>MADE IN CHINA</b>	

REV - 00  
03/2013

**SIMETHICONE**

simethicone capsule, liquid filled

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53345-009
<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	125 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PEPPERMINT OIL</b> (UNII: AV092KU4JH)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Product Characteristics

<b>Color</b>	green	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (OVAL)	<b>Size</b>	9mm
<b>Flavor</b>		<b>Imprint Code</b>	PC2
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:53345-009-01	1 in 1 BOX	04/15/2013	
1		25000 in 1 BAG; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M002	04/15/2013	

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

## Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.		421293287	manufacture(53345-009)

Revised: 11/2024

Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.