

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

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**SIMETHICONE CAPSULES 125 mg, liquid filled**

**Active ingredient (in each capsule)**

Simethicone 125 mg

**Purpose**

Antigas

**Uses**

for 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 4 softgels in 24 hours except under the advice and supervision of a physician

**Other information**

- store at room temperature 15°-30°C (59°-86°F)
- protect from light, heat and moisture

**Inactive ingredients**

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

Manufactured by:

Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.

Wuhan, Hubei

430206, China

**PRINCIPAL DISPLAY PANEL - Shipping Label**

SIMETHICONE CAPSULES, 125 mg

Quantity : 25000 Capsules

NDC. No : 53345-033-01

**IMPORTANT:**

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.

4.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 Sherdun Road, East Lake New Technology Development District,

Wuhan, Hubei 430206, P. R. China

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**NDC No.: 53345-033-01**

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Product:

**Simethicone Capsules 125 mg**

Each softgel contains: Simethicone 125 mg

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

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Product Code:

43-01664

Quantity:

25000 Capsules

Lot Number:

XXXXXXXX

Manufacturing Date:

xx/yyyy

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Box No.:

**IMPORTANT:**

1. Inspect immediately upon receipt.
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3. Protect from heat, humidity, and light. Do not refrigerate.
4. Store at 15-30°C (59-86°F)

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**MADE IN CHINA**

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**REV-00  
12/2014**

**SIMETHICONE**

simethicone capsule, liquid filled

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53345-033
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	125 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
WATER (UNII: 059QF0KO0R)	

**Product Characteristics**

<b>Color</b>	green	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (OVAL)	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	664
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53345-033-01	1 in 1 BOX	01/28/2015	
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 final	part332	01/28/2015	

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

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	MANUFACTURE(53345-033) , ANALYSIS(53345-033)