

**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 250 mg, liquid filled**

**Active ingredient (in each capsule)**

Simethicone 250 mg

**Purpose**

Anti-gas

**Uses**

- 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**

FD&C Blue #1, FD&C Red #40, gelatin, glycerin, 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, 250 mg

Quantity : 25000 Capsules

NDC. No : 53345-032-01

**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**

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

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

**NDC No.: 53345-032-01**

Product:

**Simethicone Capsules 250 mg**

Each softgel contains: Simethicone 250 mg

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

Product Code:

40-00028

Quantity:

20000 Capsules

Lot Number:

XXXXXXXX

Manufacturing Date:

xx/yyyy

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)

**MADE IN CHINA**

**REV-00  
12/2014**

**SIMETHICONE**

simethicone capsule, liquid filled

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53345-032
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	250 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WATER</b> (UNII: 059QF0KO0R)	

**Product Characteristics**

<b>Color</b>	purple	<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:53345-032-01	1 in 1 BOX	01/28/2015	
1		20000 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 final	part332	01/28/2015	

**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) , ANALYSIS(53345-032)