

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

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**Simethicone Capsules 180 mg**

**Active ingredient (in each capsule)**

Simethicone 180 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 as needed after a meal
- do not exceed two softgels per day 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 yellow#6, gelatin, glycerin, purified water and white edible ink

**PRINCIPAL DISPLAY PANEL - Shipping Label**

**SIMETHICONE CAPSULES, 180 mg**

Quantity : 25000 Capsules

NDC. No : 53345-036-01

**IMPORTANT:**

1. Inspect immediate 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 Shendun Road, East Lake New Technology Development District,  
Wuhan, Hubei 430206, P. R. China

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**NDC No.: 53345-036-01**

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Product:

**Simethicone Capsules 180 mg**

Each softgel contains: Simethicone 180 mg

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

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Product Code: 43-01667                      Quantity: 25000 Capsules

Lot Number: XXXXXXXX                      Manufacturing Date: MM/YYYY

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Box No.:	<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. 4. Store at 15-30°C (59-86°F)
<b>MADE IN CHINA</b>	

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**REV-00  
05/2016**

**SIMETHICONE**

simethicone capsule, liquid filled

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53345-036
<b>Route of Administration</b>	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	180 mg

Inactive Ingredients	
Ingredient Name	Strength
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	orange (clear)	Score	no score
Shape	CAPSULE (oval)	Size	10mm
Flavor		Imprint Code	667
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53345-036-01	1 in 1 BOX	07/25/2016	
1		25000 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	07/25/2016	

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

Establishment			
Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd		421293287	manufacture(53345-036)