

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.

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

Humanwell PuraCap Pharmaceutical (Wuhan) Ltd.

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

NDC No.: 53345-036-01

Product:

Simethicone Capsules 180 mg

Each softgel contains: Simethicone 180 mg

CAUTION: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING

Product Code:

43-01667

Quantity:

25000 Capsules

Lot Number:

XXXXXXXX

Manufacturing Date:

MM/YYYY

Box No.:

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)

MADE IN CHINA

REV-00

05/2016

SIMETHICONE

simethicone capsule, liquid filled

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:53345-036

Route of Administration

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 final	part332	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) , analysis(53345-036)

Revised: 7/2016

Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd