

SIMETHICONE- simethicone capsule, liquid filled
Humanwell PuraCap Pharmaceutical (Wuhan), 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 125 mg, liquid filled

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 immediately 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, 2nd 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: 40-00002	Quantity: 25000 Capsules
Lot No.: 0000000	Manufacturing Date: 00/0000
Box No.: X	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.
MADE IN CHINA	

**REV - 00
03/2013**

SIMETHICONE

simethicone capsule, liquid filled

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:53345-009

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	125 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
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)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part332	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) , ANALYSIS(53345-009)