

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 250 mg

Drug Facts

Active ingredient (in each softgel)

Simethicone 250 mg

Purpose

Anti-gas

Use

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

D&C red # 33, FD&C blue # 1, gelatin, glycerin, purified water and white edible ink

PRINCIPAL DISPLAY PANEL - Shipping Label

Simethicone Capsules 250 mg

NDC 53345-032-02

Quantity: 12 Capsules per blister

124 Blisters per box

IMPORTANT:

Inspect immediately upon receipt.

This is a bulk shipment, intended for further processing only.

Protect from heat, humidity, and light. Do not refrigerate.

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.: 53345-032-02

Product:

Simethicone Capsules 250 mg

Each softgel contains: Simethicone 250 mg

CAUTION: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING

Product Code:

40-00028

Quantity:

12 Capsules per blister


124 Blisters per box

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:53345-032

Route of Administration

ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	250 mg

Inactive Ingredients

Ingredient Name	Strength
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	purple (clear)	Score	no score
Shape	capsule (oval)	Size	13mm
Flavor		Imprint Code	PC31
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53345-032-02	124 in 1 BOX	06/30/2016	
1		12 in 1 BLISTER PACK; 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	06/30/2016	

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

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd		421293287	manufacture(53345-032) , analysis(53345-032)

Revised: 11/2019

Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd