

SIMETHICONE- simethicone 180 mg capsule, liquid filled
SHANDONG ROSEMED BIOOHARM LLC

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.

Other information

store at room temperature 59° - 86°F (15° - 30°C)

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

Inactive ingredients

FD&C yellow #6, gelatin, glycerin, purified water and white edible ink

keep out of reach of children

Keep out of reach of children.

Product:

Simethicone Capsules 180 mg

Each softgel contains: Simethicone 180 mg

CAUTION: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING

Product Code:

43-01687

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	

SIMETHICONE

simethicone 180 mg capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84328-002
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
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Product Characteristics

Color	orange	Score	score with uneven pieces
Shape	CAPSULE ((oval))	Size	10mm

Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84328-002-01	1 in 1 BOX	08/26/2024	
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	08/26/2024	

Labeler - SHANDONG ROSEMED BIOOHARM LLC (416829348)

Registrant - SHANDONG ROSEMED BIOOHARM LLC (416829348)

Establishment

Name	Address	ID/FEI	Business Operations
SHANDONG ROSEMED BIOOHARM LLC		416829348	manufacture(84328-002)

Revised: 8/2024

SHANDONG ROSEMED BIOOHARM LLC