

SIMETHICONE- dimethicone capsule, liquid filled
SPIRIT PHARMACEUTICALS,LLC

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 USP 180 MG

Drug Facts

Active ingredient (per softgel)

Simethicone 180 mg

Purpose

Antigas

Use

for the relief of

- pressure and bloating commonly referred to as gas

Warnings

Keep out of reach of children.

Directions

- adults: swallow with water 1 or 2 softgels as needed after meals and at bedtime
- do not exceed 2 softgels in 24 hours except under the advice and supervision of a physician

Other information

- store at a controlled room temperature 20-25°C (68-77°F)
- protect from heat and moisture

Inactive ingredients

FD&C yellow 6, gelatin, glycerin, hypromellose, peppermint oil, purified water, sorbitol, titanium dioxide

PRINCIPAL DISPLAY PANEL - Shipping Label

SIMETHICONE CAPSULES USP 180MG

Each Softgel Contains:

(Simethicone USP 180 mg)

LOT NO :

MFG DATE :

GROSS WT. :

NDC NO : 68210-1902

QUANTITY :

EXP DATE :

CRTN :

WARNING:

KEEP OUT OF REACH OF CHILDREN

STORE CONTROLLED ROOM TEMPERATURE OF 59° - 86°F (15° - 30°C)

PROTECT FROM LIGHT, MOISTURE AND FREEZING

**THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY.
CONTENTS SHOULD BE APPROVED, REPACKAGED IMMEDIATELY AND LABELED IN
STRICT CONFORMANCE**

WITH

THE F.D & C.ACT AND REGULATIONS THEREUNDER.

MANUFACTURED BY:

SOFTGEL HEALTHCARE PVT LIMITED

INDIA

LABELLER CODE : 35916

LIC NO. : TN/DRUGS/00002124

MANUFACTURED FOR:

SPIRIT PHARMACEUTICALS LLC


225 LINCOLN HWY, STE 205

FAIRLESS HILLS, PA 19030

PH.# 215 943 4000

FAX.# 215 943 4039

CAUTION : "FOR MANUFACTURING, PROCESSING OR REPACKING"

	SIMETHICONE CAPSULES USP 180MG <u>Each Softgel Contains:</u> (Simethicone USP 180 mg)
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MANUFACTURED BY: SOFTGEL HEALTHCARE PVT LIMITED INDIA LABELLER CODE : 35916 LIC NO. : TN/DRUGS/00002124	MANUFACTURED FOR: SPIRIT PHARMACEUTICALS LLC 225 LINCOLN HWY, STE 205 FAIRLESS HILLS, PA 19030 PH.# 215 943 4000 FAX.# 215 943 4039
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SIMETHICONE

dimethicone capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-1902
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
GLYCERIN (UNII: PDC6A3C0OX)	
GELATIN (UNII: 2G86QN327L)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0K00R)	
HYPROMELLOSE (UNII: 3NXW29V3WO)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
PEPPERMINT OIL (UNII: AV092KU4JH)	

Product Characteristics

Color	ORANGE	Score	no score
Shape	OVAL	Size	10mm
Flavor		Imprint Code	P10
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-1902-1	1 in 1 BOX		
1		10 in 1 BAG		
2	NDC:68210-1902-2	1 in 1 BOX		
2		30 in 1 BAG		
3	NDC:68210-1902-3	1 in 1 BOX		
3		1000 in 1 BAG		
4	NDC:68210-1902-4	1 in 1 BOX		
4		16000 in 1 BAG		
5	NDC:68210-1902-5	1 in 1 BOX		
5		20000 in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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Labeler - SPIRIT PHARMACEUTICALS,LLC (179621011)**Establishment**

Name	Address	ID/FEI	Business Operations
SOFTGEL HEALTHCARE PVT LTD		675584180	MANUFACTURE

Revised: 12/2009

SPIRIT PHARMACEUTICALS,LLC