

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 125MG

Drug Facts

Active ingredient (per softgel)

Simethicone 125 mg

Purpose

Antigas

Use

for the relief of

- pressure, bloating, and fullness 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 4 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 light, heat and moisture

Inactive ingredients

D&C yellow 10, FD&C blue 1, FD&C red 40, gelatin, glycerin, hypromellose, peppermint oil, purified water, sorbitol, titanium dioxide

PRINCIPAL DISPLAY PANEL - 125 mg Label

SIMETHICONE CAPSULES USP 125MG

Each Softgel Contains:

(Simethicone USP 125 mg)

LOT NO :	QUANTITY:
DRUM :	NDC NO : 68210-1901-
NO :	

MFG :
DATE :

EXP DATE :

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"

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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:68210-1901

Route of Administration ORAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
GELATIN (UNII: 2G86QN327L)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-1901-1	10 in 1 BOX		
2	NDC:68210-1901-2	30 in 1 BOX		
3	NDC:68210-1901-3	1000 in 1 BOX		
4	NDC:68210-1901-4	16000 in 1 BOX		
5	NDC:68210-1901-5	20000 in 1 BOX		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part332	03/01/2010	

Labeler - SPIRIT PHARMACEUTICALS,LLC (179621011)

Establishment

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