

SIMETHICONE - dimethicone capsule, liquid filled
Softech Pharma Pvt. 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

Active ingredient (per soft gel)

Simethicone 125 mg

Purpose

Antigas

Uses

Relieves pressure and bloating commonly referred to as gas

Warnings

Keep out of reach of children

Directions

- Do not exceed 4 softgels in 24 hours
- Adults: swallow with water 1 or 2 softgels as needed after meals and at bedtime

Other information

store at 20⁰ - 25⁰C

Inactive ingredients

D and C yellow 10, FD and C blue 1, FD and C red 40, gelatin, glycerin, mannitol, peppermint oil, purified water, sorbitan, sorbitol, titanium dioxide

Simethicone Capsules, 125 mg

Each Capsule Contains:
Simethicone, USP 125 mg

Lot No. :
Mfg. Date :
Exp. Date :

Quantity : 5000 Capsules
NDC Code : 48769-113-99

WARNING :
KEEP OUT OF THE REACH OF CHILDREN

STORE AT CONTROLLED ROOM TEMPERATURE OF 59-77°F (15-25 °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 FDA AND REGULATIONS THEREUNDER.

Manufactured By : Softech Pharma Pvt. Ltd.
MANUFACTURER CODE No.: DD/417
LABELER CODE # 48769

Manufactured For :
Raritan Pharmaceuticals
8 Joanna Court, East Brunswick, NJ 08816

CAUTION : "FOR MANUFACTURING, PROCESSING OR REPACKING."

Keep out of Reach of Children

SIMETHICONE

dimethicone capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:48769-113
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
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
MANNITOL (UNII: 3OWL53L36A)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	green	Score	no score
Shape	OVAL	Size	5mm
Flavor		Imprint Code	RP113
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:48769-113-99	5000 in 1 BAG		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part332	01/15/2012	

Labeler - Softech Pharma Pvt. Ltd (677111277)

Establishment			
Name	Address	ID/FEI	Business Operations
Softech Pharma Pvt. Ltd		677111277	manufacture