

**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.*

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**SIMETHICONE Capsules 180 mg**

**Active ingredient (in each softgel)**

Simethicone 180 mg

**Purpose**

Antigas

**Uses**

Relieves bloating, pressure or fullness commonly referred to as gas

**Warnings**

**Stop use and ask doctor if condition persists**

Keep out of Reach of Children

**Directions**

- Swallow one or two softgels as needed after a meal
- Do not exceed two softgels per day except under the advise and supervision of a physician

**Other Information**

- Each softgel contains: potassium 5 mg
- Store at 20<sup>0</sup> - 25<sup>0</sup>C

**Inactive ingredients:**

FD and C Red No. 40, FD and C yellow No. 6, Gelatin, Glycerol

## Simethicone Capsules, 180 mg

Each Capsule Contains:  
Simethicone, USP 180 mg

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

Quantity : 1000 Capsules  
NDC Code : 48769-112-99

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."

## SIMETHICONE

dimethicone capsule, liquid filled

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:48769-112
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
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	

**Product Characteristics**

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	8mm
<b>Flavor</b>		<b>Imprint Code</b>	RP112
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:48769-112-99	1000 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

Revised: 6/2012

Softech Pharma Pvt. Ltd.