

**SIMETHICONE 80 MG- simethicone tablet, chewable  
REMEDYREPACK INC.**

*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 80 mg**

***Drug Facts***

***Use***

relieves bloating, pressure and fullness commonly referred to as gas

***Warnings***

**Keep out of reach of children**

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***Directions***

- thoroughly chew 1-2 tablets as needed after meals and at bedtime
- do not take more than 6 tablets per day

***Other information***

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

***Inactive ingredients***

compressible sugar, dextrose, maltodextrin, microcrystalline cellulose, peppermint flavor, Silicon dioxide, sorbitol, stearic acid

***Questions or comments?***

call **516-341-0666**, 8:30 am to 4:30 pm ET, Monday - Friday

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS  
BROKEN OR MISSING**

Repackaged and Distributed By:

Remedy Repack, Inc.

625 Kolter Dr. Suite #4 Indiana, PA 1-724-465-8762

***Active ingredient (in each chewable tablet)***

Simethicone 80 mg

***Purpose***

Antiflatulent

DRUG: Simethicone 80 mg

GENERIC: Simethicone

DOSAGE: TABLET, CHEWABLE

ADMINISTRATION: ORAL

NDC: 70518-3123-0

NDC: 70518-3123-1

COLOR: white

SHAPE: ROUND

SCORE: No score

SIZE: 13 mm

IMPRINT: AP;019

PACKAGING: 1 in 1 POUCH

OUTER PACKAGING: 100 in 1 BOX

ACTIVE INGREDIENT(S):

- DIMETHICONE 80mg in 1

INACTIVE INGREDIENT(S):

- CELLULOSE, MICROCRYSTALLINE
- SILICON DIOXIDE
- MALTODEXTRIN
- SORBITOL
- STEARIC ACID
- SUCROSE
- DEXTROSE
- PEPPERMINT

# Simethicone

80 mg

Chewable Tablet

QTY: 100



NDC #: 70518-3123-00

Expires:

LOT #:

Source NDC: 69618-0033-01



MFG: Reliable 1 Laboratories, Valley Stream, NY 11580

Keep this and all medication out of the reach of children

Directions For Use: See Package Insert

Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F) [See USP]

Repackaged by: RemedyRepack Inc., Indiana, PA 15701, 724.465.8762

**NOT FOR RETAIL SALE**

# Simethicone

80 mg

Chewable Tablet

QTY: 1



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Expires:

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Repackaged by: RemedyRepack Inc., Indiana, PA 15701, 724.465.8762

**NOT FOR RETAIL SALE**

## SIMETHICONE 80 MG

simethicone tablet, chewable

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70518-3123(NDC:69618-033)
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	80 mg

### Inactive Ingredients

Ingredient Name	Strength
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<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>DEXTROSE</b> (UNII: IY9XDZ35W2)	
<b>PEPPERMINT</b> (UNII: V95R5KMY2B)	

### Product Characteristics

<b>Color</b>	white (Off White)	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	13mm
<b>Flavor</b>		<b>Imprint Code</b>	AP;019
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70518-3123-0	100 in 1 BOX	06/15/2021	
1	NDC:70518-3123-1	1 in 1 POUCH; Type 0: Not a Combination Product		



# SIMETHICONE 80MG CHEW TABLET

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part332	06/15/2021	

**Labeler** - REMEDYREPACK INC. (829572556)

Revised: 6/2021

REMEDYREPACK INC.