

**SIMETHICONE 125 MG- simethicone tablet, chewable  
ATLANTIC BIOLOGICALS CORP.**

*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 125 mg**

***Drug Facts***

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

Simethicone 125 mg

Antiflatulent

***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 4 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 -4:30 pm ET, Monday - Friday

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

\*Reliable 1 Laboratories LLC is not affiliated with the owner of the trademark Mylanta®

Distributed by:

**ATLANTIC BIOLOGICALS CORP.**

**MIAMI, FL 33179**

**NDC 17856-0137-01**

**Simethicone 125 mg**

**ANTIFLATULENT**

**100ct CHEWABLE TABLETS**

**17856-0137-01**  
**SIMETHICONE**  
**125 MG TAB**



See package insert for indications and dosage schedule

Store at room temperature 15°-30°C ( 59°-86°F )  
\*\* Keep this and all medication out of the reach  
of children\*\*



17856-0137-01

Dosage 125 MG

SIMETHICONE

Qty: 50 Chewable  
Tablets



GTIN: 00117856013716

S/N: 01856701

Exp: 03/28/23

Lot: 018567



Packaged by: Unit Dose Solutions  
Morrisville, NC 27560

Distributed by: Atlantic Biologicals Corp.  
Miami FL 33179

Rev.08/21

**Call to Reorder: 800.509.7592**

## SIMETHICONE 125 MG

simethicone tablet, chewable

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:17856-0137(NDC:69618-032)
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	125 mg

**Inactive Ingredients**

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

**Product Characteristics**

<b>Color</b>	white (Off white)	<b>Score</b>	2 pieces
<b>Shape</b>	ROUND	<b>Size</b>	16mm
<b>Flavor</b>		<b>Imprint Code</b>	AP;040
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17856-0137-1	100 in 1 BOX, UNIT-DOSE	09/29/2022	
1	NDC:17856-0137-2	1 in 1 POUCH; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part332	04/25/2018	

**Labeler** - ATLANTIC BIOLOGICALS CORP. (047437707)**Establishment**

Name	Address	ID/FEI	Business Operations
UNIT DOSE SOLUTIONS		360804194	repack(17856-0137)