

**MYLICON- simethicone suspension**  
**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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**hst infants gas relief**

**Active ingredient (in each 0.3 mL)**

Simethicone 20 mg

**Purpose**

Antigas

**Use**

relieves the symptoms referred to as gas

**Warnings**

**Keep out of reach of children.** In case of overdose, get medical help or contact a poison control center right away.

**Directions**

- shake well before using
- all dosages may be repeated as needed, after meals and at bedtime, or as directed by a physician
- do not exceed 12 doses per day
- fill enclosed dropper to recommended dosage level and dispense liquid slowly into baby's mouth, toward the inner cheek dosage can also be mixed with 1 oz. of cool water, infant formula or other suitable liquids
- clean dropper well after each use and replace original cap on bottle

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Age (years)	Weight (lbs)	Dose
infants (under 2)	under 24	0.3 mL
children (2 and over)	24 and over	0.6 mL

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**Other information**

- TAMPER-EVIDENT: Do not use if foil seal under the cap is broken or punctured.
- store at room temperature
- do not freeze

- see bottom panel for lot number and expiration date

**Inactive ingredients**

carboxymethylcellulose sodium, citric acid, flavor, maltitol, microcrystalline cellulose, purified water, sodium benzoate, sodium citrate, xanthan gum

**Questions or comments?**

**1-800-540-3765**

**DISTRIBUTED BY:**

ATLANTIC BIOLOGICALS CORP.

MIAMI, FL 33179

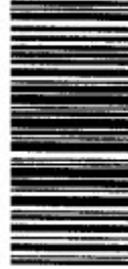
**Package Label**

**17856-0799-01**  
**INFANTS' GAS RELIEF**  
**(SIMETHICONE)**  
**ORAL SUSPENSION USP**  
**20MG / 0.3 ML**  
**DELIVERS 0.3 ML**



See package insert for indications and dosage schedule

Store at Room Temperature. Do not freeze. DYE FREE  
KEEP OUT OF THE REACH OF CHILDREN.



17856079901

**17856-0799-01**

**Dosage 0.3ML**

**INFANTS' GAS RELIEF**

**Qty: 120 ENFit SYRINGES**

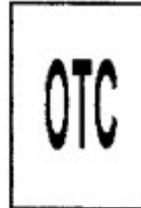


**GTIN: 00117856079910**

**S/N: 01985601**

**Exp: 10/03/23**

**Lot: 019856**



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**

**17856-0799-03**  
**INFANTS' GAS RELIEF**  
**(SIMETHICONE)**  
**ORAL SUSPENSION USP**  
**40 MG / 0.6 ML**  
**DELIVERS 0.6 ML**



See package insert for indications and dosage schedule



Store at Room Temperature. Do not freeze. DYE FREE  
 KEEP OUT OF THE REACH OF CHILDREN.

**17856-0799-03**

**Dosage 0.6 ML**

**INFANTS' GAS RELIEF**

**Qty: 120 ENFit SYRINGES**



**GTIN: 00117856079934**  
**S/N: 01985901**  
**Exp: 10/03/23**  
**Lot: 019859**



Packaged by: Unit Dose Solutions  
 Morrisville, NC 27560

Distributed by: Atlantic Biologicals Corp,  
 Miami FL 33179

Rev.08/21

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**MYLICON**

simethicone suspension

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:17856-0799(NDC:57896-798)
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name		Basis of Strength	Strength	
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)		DIMETHICONE	20 mg in 0.3 mL	
<b>Inactive Ingredients</b>				
Ingredient Name			Strength	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)				
MALTITOL (UNII: D65DG142WK)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
WATER (UNII: 059QF0KO0R)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SODIUM CITRATE (UNII: 1Q73Q2JULR)				
XANTHAN GUM (UNII: TTV12P4NEE)				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17856-0799-1	120 in 1 BOX, UNIT-DOSE	04/06/2023	
1		0.3 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:17856-0799-2	120 in 1 BOX, UNIT-DOSE	04/06/2023	
2		0.3 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
3	NDC:17856-0799-3	120 in 1 BOX, UNIT-DOSE	04/06/2023	
3		0.6 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
4	NDC:17856-0799-4	120 in 1 BOX, UNIT-DOSE	04/06/2023	
4		0.6 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
5	NDC:17856-0799-5	60 in 1 BOX, UNIT-DOSE	04/06/2023	
5		1.2 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part332	05/01/2014		
<b>Labeler - ATLANTIC BIOLOGICALS CORP. (047437707)</b>				
<b>Establishment</b>				
Name	Address	ID/FEI	Business Operations	

Revised: 5/2023

ATLANTIC BIOLOGICALS CORP.