

**INFANTS- simethicone suspension/ drops**  
**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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**Rugby® Infants' Gas Relief Simethicone Drops**

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

Simethicone 20 mg

**Purpose**

Antigas

**Uses**

relieves the discomfort of infant gas frequently caused by air swallowing or certain formulas or foods

**Warnings**

**Keep out of reach of children.**

**Overdose warning: In case of overdose get medical help or contact a Poison Control Center right away at 1-800-222-1222. Quick medical attention is critical even if you do not notice any signs or symptoms.**

**Directions**

- **shake well before using**
- find right dose on chart below. If possible, use weight to dose; otherwise, use age.
- only use the enclosed syringe. **Do not use other syringe, dropper, spoon or dosing device when giving this medicine to your child.**
- remove cap and insert syringe into the bottle.
- pull syringe up until filled to the prescribed level, simply push syringe back until you have reached the described level. Slowly dispense the liquid into your child's mouth (towards inner cheek).
- 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.
- dosage can also be mixed with 1 oz. cool water, infant formula or other suitable liquids.
- Replace cap tightly to maintain child resistance
- mL = milliliter

<b>Age (yr)</b>	<b>Weight (lb)</b>	<b>Dose (mL)</b>
infants under 2	under 24	0.3
children over 2	over 24	0.6

### **Other information**

- **tamper evident: do not use if printed seal under cap is broken or missing**
- Store at room temperature
- do not freeze
- see bottom panel for lot number and expiration date

### **Inactive ingredients**

carboxymethylcellulose sodium, citric acid, flavors, microcrystalline cellulose, polysorbate 60, potassium sorbate, purified water, sodium benzoate, sorbitan monostearate, sorbitol, xanthan gum

### **Questions or comments?**

1-800-645-2158

### **Principal Display Panel**

Infants'

#### **Simethicone Drops**

Antigas

•Dye-free•Non-staining formula•No Saccharin•No Artificial Color•No Artificial Flavor

Distributed by:

ATLANTIC BIOLOGICALS CORP.

MIAMI, FL 33179

**17856-1303-01**  
Infants' Simethicone Drops  
Antigas/ Dye Free  
20 mg / 0.3 mL  
Delivers 0.3 mL



**17856-1303-02**  
Infants' Simethicone Drops  
Antigas/ Dye Free  
20 mg / 0.3 mL  
Delivers 0.3 mL

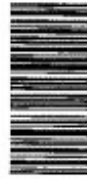


See package insert for indications and dosage schedule

See package insert for indications and dosage schedule

Store at room temperature. Do not freeze.  
KEEP OUT OF THE REACH OF CHILDREN

Store at room temperature. Do not freeze.  
KEEP OUT OF THE REACH OF CHILDREN



17856130301



17856130302

**17856-1303-01**      **Dosage: 0.3 mL**

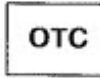
**17856-1303-02**      **Dosage: 0.3 mL**

Infants' Simethicone Drops    Qty: 120 Enfit Syring

Infants' Simethicone Drops    Qty: 120 Syringes



GTIN: 00117856130307  
S/N: 01445501  
Exp: 12/28/21  
Lot: 014455



GTIN: 00117856130321  
S/N: 01445601  
Exp: 12/28/21  
Lot: 014456



Packaged by: Unit Dose Solutions  
Morrisville, NC 27560

Distributed by: AtlanticBiologics Corp  
Miami FL 33179

Packaged by: Unit Dose Solutions  
Morrisville, NC 27560

Distributed by: AtlanticBiologics Corp  
Miami FL 33179

Rev. 09/19

**Call to Reorder: 800.509.7592**

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**17856-1303-03**  
Infants' Simethicone Drops  
Antigas/ Dye Free  
40 mg / 0.6 mL  
Delivers 0.6 mL



**17856-1303-04**  
Infants' Simethicone Drops  
Antigas/ Dye Free  
40 mg / 0.6 mL  
Delivers 0.6 mL

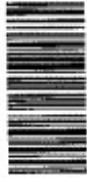


See package insert for indications and dosage schedule

See package insert for indications and dosage schedule

Store at room temperature. Do not freeze.  
KEEP OUT OF THE REACH OF CHILDREN

Store at room temperature. Do not freeze.  
KEEP OUT OF THE REACH OF CHILDREN



17856130303



17856130304

**17856-1303-03**      **Dosage: 0.6 mL**

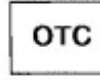
**17856-1303-04**      **Dosage: 0.6 mL**

Infants' Simethicone Drops    Qty: 120 Enfit Syring

Infants' Simethicone Drops    Qty: 120 Syringes



GTIN: 00117856130338  
S/N: 01445701  
Exp: 12/28/21  
Lot: 014457



GTIN: 00117856130345  
S/N: 01445801  
Exp: 12/28/21  
Lot: 014458



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Morrisville, NC 27560

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Miami FL 33179

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**17856-1303-05**  
**Infants' Simethicone Drops**  
**Antigas/ Dye Free**  
**80 mg / 1.2 mL**  
**Delivers 1.2 mL**



See package insert for indications and dosage schedule



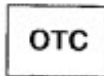
Store at room temperature. Do not freeze.  
**KEEP OUT OF THE REACH OF CHILDREN**

**17856-1303-05                      Dosage: 1.2 mL**

**Infants' Simethicone Drops      Qty: 60 Enfit Syringes**



GTIN: 00117856130352  
 S/N: 01445901  
 Exp: 12/26/21  
 Lot: 014459



Packaged by: Unit Dose Solutions  
 Morrisville, NC 27560

Distributed by: AtlanticBiologicals Corp,  
 Miami FL 33178

Rev. 09/19

**Call to Reorder: 800.509.7592**

**CUT ME OFF**

50608189871



DIST BY: ATLANTIC BIOLOGICALS CORP  
 MFG: MAJOR LOT: XBD020  
 PKG BY: UDS-MOR LOT: 370766

**Infants' GAS RELIEF DROPS (SIMETHICONE)**  
**Oral Suspension Antigas/Dye Free**  
**(20 mg/ 0.3 ml) DELIVERS 80 mg/ 1.2ml**  
**Unit Dose Enfit Syringe**  
**EXPIRATION: 12/25/2021**

## INFANTS

simethicone suspension/ drops

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:17856-1303(NDC:0536-1303)
<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	20 mg in 0.3 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM</b> (UNII: K679OBS311)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SORBITAN MONOSTEARATE</b> (UNII: NVZ4I0H58X)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

### Product Characteristics

<b>Color</b>	PINK	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17856-1303-1	120 in 1 BOX, UNIT-DOSE	06/30/2021	
1		0.3 mL in 1 SYRINGE; Type 0: Not a Combination Product		
2	NDC:17856-1303-2	120 in 1 BOX, UNIT-DOSE	06/30/2021	
2		0.3 mL in 1 SYRINGE; Type 0: Not a Combination Product		
3	NDC:17856-1303-3	120 in 1 BOX, UNIT-DOSE	06/30/2021	
3		0.6 mL in 1 SYRINGE; Type 0: Not a Combination Product		
4	NDC:17856-1303-4	120 in 1 BOX, UNIT-DOSE	06/30/2021	
4		0.6 mL in 1 SYRINGE; Type 0: Not a Combination Product		
5	NDC:17856-1303-5	60 in 1 BOX, UNIT-DOSE	06/30/2021	
5		1.2 mL in 1 SYRINGE; 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	09/01/2020	

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

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## Establishment

Name	Address	ID/FEI	Business Operations
ATLANTIC BIOLOGICALS CORP.		047437707	relabel(17856-1303) , repack(17856-1303)

Revised: 6/2021

ATLANTIC BIOLOGICALS CORP.