

**GAS RELIEF- 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 infant drops**

**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 inner cheek
- may be mixed with 1 oz of water, infant formula or other suitable liquid
- for best results, clean dropper after each use and replace original cap

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

**Other information**

- store at room temperature
- do not freeze
- see bottom panel for lot number and expiration date
- **TAMPER-EVIDENT: Do not use if foil seal under cap is broken or missing**

**Inactive ingredients**

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

**Questions or comments?**

**1-800-645-2158**

**DISTRIBUTED BY:**

ATLANTIC BIOLOGICALS CORP.

MIAMI, FL 33179

**package Label**

**17856-2220-01**

**INFANT GAS RELIEF DROPS**

**(SIMETHICONE)**

**40MG/0.6ML**

**DELIVERS 0.6ML**



See package insert for indications and dosage schedule

Store at room temperature. Do not freeze.  
ANTIGAS / DRY FREE  
KEEP OUT OF THE REACH OF CHILDREN



**17856-2220-01**

**Dosage: 40MG/0.6ML**

**INFANT GAS RELIEF  
DROPS (SIMETHICONE)**

**Qty: 120 SYRINGES**



**GTIN: 00117856222019**

**S/N: 01118501**

**Exp: 02/05/21**

**Lot: 011195**

**OTC**

Packaged by: Unit Dose Solutions  
Morrisville, NC 27560

Distributed by: Atlantic Biologicals Corp.  
Miami FL 33179

Rev. 09/19

**Call to Reorder: 800.509.7592**

**17856-2220-02**  
**INFANT GAS RELIEF DROPS**   
**(SIMETHICONE)**  
**20MG/0.3ML**  
**DELIVERS 0.3ML**

See package insert for indications and dosage schedule

Store at room temperature. Do not freeze.  
ANTIGAS / DRY FREE  
KEEP OUT OF THE REACH OF CHILDREN



**17856-2220-02**

**Dosage: 20MG/0.3ML**

**INFANT GAS RELIEF  
DROPS (SIMETHICONE)**

**Qty: 120 SYRINGES**



**GTIN: 00117856222026**

**S/N: 01118601**

**Exp: 02/05/21**

**Lot: 011186**

**OTC**

Packaged by: Unit Dose Solutions  
Merriville, NC 27560

Distributed by: Atlantic Biologicals Corp.  
Miami FL 33179

Rev.09/19

**Call to Reorder: 800.509.7592**

**17856-2220-03**

**INFANT GAS RELIEF DROPS**

**(SIMETHICONE)**

**40MG/0. 0.6ML**

**DELIVERS 0.6ML**



See package insert for indications and dosage schedule

Store at room temperature. Do not freeze.  
ANTIGAS / DRY FREE  
KEEP OUT OF THE REACH OF CHILDREN



**17856-2220-03**

**Dosage: 40MG/0.6ML**

**INFANT GAS RELIEF  
DROPS (SIMETHICONE)**

**Qty: 120 ENFit  
SYRINGES**



GTIN: 00117856222033

S/N: 01118701

Exp: 02/05/21

Lot: 011187

**OTC**

Packaged by: Unit Dose Solutions  
Morrisville, NC 27560

Distributed by: Atlantic Biologicals Corp.  
Miami, FL 33179

Rev. 09/19

**Call to Reorder: 800.509.7592**



Lodges



17856222004

17856222004

**INFANT GAS RELIEF  
DROPS (SIMETHICONE)**

Qty: 120 ENFit  
SYRINGES



S/N: 01118801

Exp: 02/05/21

Lot: 011188

**OTC**

Packaged by Unit Dose Solutions  
Morrisville, NC 27560

Distributed by: Atlantic Biologicals Corp.  
Miami FL 33179

Rev.09/19

**Call to Reorder: 800.509.7592**

DELIVERS 1.2ML

Store at room temperature. Do not freeze.  
ANTIGAS / DRY FREE  
KEEP OUT OF THE REACH OF CHILDREN



Qty: 60 ENFit  
SYRINGES



Lot: 011199

OTC

Distributed by: Atlantic Biologicals Corp.  
Miami Fl 33179

**Call to Reorder: 800.509.7592**

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
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)				
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
MALTITOL (UNII: D65DG142WK)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
WATER (UNII: 059QF0KO0R)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SODIUM CITRATE (UNII: 1Q73Q2JULR)				
XANTHAN GUM (UNII: TTV12P4NEE)				
Product Characteristics				
Color	white (off-white)		Score	
Shape			Size	
Flavor	CHERRY		Imprint Code	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17856-2220-1	120 in 1 BOX, UNIT-DOSE	08/17/2020	
1		0.6 mL in 1 SYRINGE; Type 0: Not a Combination Product		
2	NDC:17856-2220-2	120 in 1 BOX, UNIT-DOSE	08/17/2020	
2		0.3 mL in 1 SYRINGE; Type 0: Not a Combination Product		
3	NDC:17856-2220-3	120 in 1 BOX, UNIT-DOSE	08/17/2020	
3		0.6 mL in 1 SYRINGE; Type 0: Not a Combination Product		
4	NDC:17856-2220-4	120 in 1 BOX, UNIT-DOSE	08/17/2020	
4		0.3 mL in 1 SYRINGE; Type 0: Not a Combination Product		
5	NDC:17856-2220-5	60 in 1 BOX, UNIT-DOSE	08/17/2020	
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		12/01/2010	

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

Establishment			
Name	Address	ID/FEI	Business Operations
ATLANTIC BIOLOGICALS CORP.		047437707	relabel(17856-2220, 17856-2220)