

**INFANTS GAS RELIEF- simethicone suspension/ drops**  
**Atlantic Biologicals Corps**

*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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**MAJOR INFANT 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 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

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

**Other information**

- **TAMPER-EVIDENT:** Do not use if foil 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, maltitol, microcrystalline cellulose, flavor, purified water, sodium benzoate, sodium citrate, xanthan gum

**Questions or comments?**

**(800)616-2471**

**HOW SUPPLIED**

Product: 17856-5894

NDC: 17856-5894-1 10 mL in a CUP

NDC: 17856-5894-4 1.2 mL in a DOSE PACK / 60 in a CASE

**INFANTS GAS RELIEF (SIMETHICONE) SUSPENSION/ DROPS**

NDC 17856-5894-03

**NDC 17856-5894-03**

**INFANTS' GAS RELIEF DROPS  
(SIMETHICONE)**

Delivers 20 mg per 0.3 mL ORAL SYRINGE

ANTIGAS/DYE-FREE

**UNIT DOSE**

**PACKAGING INFORMATION:**

Dosage per Oral Syringe: 0.3 mL

Oral Syringe(s) per Case: 120

See Package Insert for Drug Facts.

Other Information:

Store at Room Temperature. Do Not Freeze.

SHAKE WELL BEFORE USING

KEEP INFANTS' GAS RELIEF DROPS AND  
ALL MEDICINES OUT OF THE REACH OF CHILDREN

Repackaged by: Unit Dose Solutions, Inc., Morrisville, NC 27560

Distributed by: Atlantic Biologicals Corp.  
20101 N.E. 16th Place  
Miami, FL 33179

\*Retain box label and package insert for drug information.

**Questions or Comments:**

**Call 1-800-509-7592**

Lot No: XXXXXX

MFG Lot No: XXXXXXX

Exp Date: XX/XX/XXXX



17856589403

**NDC 17856-5894-04**  
**INFANTS' GAS RELIEF DROPS**  
**(SIMETHICONE)**

(20 mg PER 0.3 mL)

Delivers 80 mg per 1.2 mL ENFIT SYRINGE

**ANTIGAS/DYE-FREE**

**UNIT DOSE**

**PACKAGING INFORMATION:**

Dosage per Oral Syringe: 1.2 mL

Oral Syringe(s) per Case: 60

See Package Insert for Drug Facts.

**Other Information:**

Store at Room Temperature. Do Not Freeze.

**SHAKE WELL BEFORE USING**

**KEEP INFANTS' GAS RELIEF DROPS AND  
ALL MEDICINES OUT OF THE REACH OF CHILDREN**

Repackaged by: Unit Dose Solutions, Inc., Morrisville, NC 27560

Distributed by: Atlantic Biologicals Corp.

20101 N.E. 16th Place

Miami, FL 33179

\*Retain box label and package insert for drug information.

**Questions or Comments:**

**Call 1-800-509-7592**

**Lot No: 337474**

**MFG Lot No: TBD027**

**Exp Date: 10/17/2018**



17856589404

**INFANTS GAS RELIEF (SIMETHICONE) SUSPENSION/ DROPS**

NDC 17856-5894-07

**NDC 17856-5894-07**

**INFANTS' GAS RELIEF DROPS**

**SIMETHICONE**

(20 mg PER 0.3 mL)

Delivers 20 mg per 0.3 mL ENFIT SYRINGE

**ANTIGAS/DYE-FREE**

**UNIT DOSE**

**PACKAGING INFORMATION:**

Dosage per Oral Syringe: 0.3 mL

Oral Syringe(s) per Case: 120

See Package Insert for Drug Facts.

Other Information:

Store at Room Temperature.  
Do not Freeze.

**KEEP INFANTS' GAS RELIEF DROPS SIMETHICONE AND  
ALL MEDICINES OUT OF THE REACH OF CHILDREN**

Repackaged by: Unit Dose Solutions, Inc., Morrisville, NC 27560

Distributed by: Atlantic Biologicals Corp.  
20101 N.E. 16th Place  
Miami, FL 33179

\*Retain box label and package insert for drug information.

**Questions or Comments:**

**Call 1-800-509-7592**

Lot No: XXXXXX  
MFG Lot No: XXXXXX  
Exp Date: XX/XX/XXXX



17856589407

**INFANTS GAS RELIEF**

simethicone suspension/ drops

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:17856-5894(NDC:0904-5894)
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	20 mg in 0.3 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
MALTITOL (UNII: D65DG142WK)	

<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>ANHYDROUS TRISODIUM CITRATE</b> (UNII: RS7A450LGA)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

### Product Characteristics

<b>Color</b>	white (off-white)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17856-5894-4	60 in 1 CASE	03/01/2018	
1		1.2 mL in 1 DOSE PACK; Type 0: Not a Combination Product		
2	NDC:17856-5894-1	10 mL in 1 CUP; Type 0: Not a Combination Product	05/01/2015	
3	NDC:17856-5894-3	.3 mL in 1 SYRINGE; Type 0: Not a Combination Product	05/18/2018	
4	NDC:17856-5894-7	120 in 1 BOX, UNIT-DOSE	10/05/2018	
4		.3 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 NOT FINAL	part356	12/07/2010	

**Labeler** - Atlantic Biologicals Corps (047437707)

### Establishment

Name	Address	ID/FEI	Business Operations
Atlantic Biologicals Corps		047437707	RELABEL(17856-5894) , REPACK(17856-5894)

Revised: 10/2018

Atlantic Biologicals Corps