# TEENY TUMMY GAS RELIEF DROPS- simethicone suspension ALTANTIC BIOLOGICAS CORP.

-----

TEENY TUMMY fast instant gas relief INFANT'S GAS RELIEF DROPS

## Active ingredient (in each 0.3 mL)

Simethicone 20 mg

## **Purpose**

**Antigas** 

#### Uses

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

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

#### Other information

- TAMPER-EVIDENT: Do not use if printed seal under 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 strawberry, Microcrystalline cellulose, Polysorbate 60, Potassium sorbate, Purified water, Sodium benzoate, Sorbitan monostearate, Sorbitol solution, Xanthan gum.

#### Questions or comments?

Call toll-free 1-877-225-6999.

**DISTRIBUTED BY:** 

ATLANTIC BIOLOGICALS CORP.

MIAMI, FL 33179

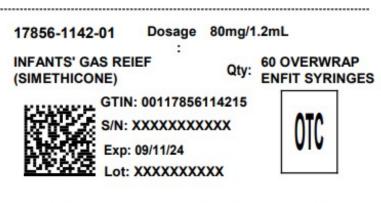
17856-1142-01 INFANTS' GAS REIEF (SIMETHICONE) ORAL SUSPENSION USP 20 mg PER 0.3 mL DELIVERS 80mg/1.2mL

See package insert for indications and dosage schedule

Infants' gas relief drops with no artifical flavors or dyes that works in minutes. Free of alcohol, gluten, and paraben. Store at room temperature and do not freeze

\*\*Keep this and all medications out of the reach of children\*\*





Packaged by:

Distributed by: Atlantic Biologicals Corp. Miami, FL 33179

Rev.08/21 Call to Reorder:



17856114201
INFANTS' GAS RELIEF
(SIMETHICONE)
ORAL SUSPENSION, USP
DELIVERS 80mg/1.2mL
20 mg PER 0.3 mL
ALCOHOL/DYE/GLUTEN FREE
EXP:XX/XX/XX LOT#XXXXX
DIST. BY
ATLANTIC BIOLOGICALS CORP.
OTC REV. 1

## **TEENY TUMMY GAS RELIEF DROPS**

simethicone suspension

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17856-1142(NDC:71399-0041)
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10)	DIMETHICONE	20 mg in 0.3 mL		

Inactive Ingredients	
Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K6790BS311)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
SORBITOL (UNII: 506T60A25R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics				
Color		Score		
Shape		Size		

Flavor	STRAWBERRY	Imprint Code	
Contains			

l	Packaging				
	#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:17856- 1142-1	60 in 1 BOX, UNIT-DOSE	09/12/2024	
	1	NDC:17856- 1142-2	1.2 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M	08/04/2023		

## Labeler - ALTANTIC BIOLOGICAS CORP. (047437707)

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
UNIT DOSE SOLUTIONS		360804194	repack(17856-1142)		

Revised: 9/2024 ALTANTIC BIOLOGICAS CORP.