

TEENY TUMMY GAS RELIEF DROPS- simethicone suspension
ATLANTIC BIOLOGICALS 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

17856-1141-01
INFANTS' GAS REIEF
(SIMETHICONE)
ORAL SUSPENSION USP
20 mg PER 0.3 mL
DELIVERS 20mg/0.3mL



See package insert for indications and dosage schedule

Infants' gas relief drops with no artificial 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



17856-1141-01 Dosage 20mg/0.3mL

INFANTS' GAS REIEF Qty: 120 ENFIT
(SIMETHICONE) SYRINGES



GTIN: 00117856114116
 S/N: XXXXXXXXXXXX
 Exp: 09/11/24
 Lot: XXXXXXXXXXXX



Packaged by:

Distributed by: Atlantic Biologicals Corp.
 Miami, FL 33179

Rev.08/21

Call to Reorder:

17856-1141-03
INFANTS' GAS REIEF
(SIMETHICONE)
ORAL SUSPENSION USP
20 mg PER 0.3 mL
DELIVERS 40mg/0.6mL



See package insert for indications and dosage schedule

Infants' gas relief drops with no artificial 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



217856114103

17856-1141-03 Dosage 40mg/0.6mL

INFANTS' GAS REIEF
(SIMETHICONE)

Qty: 120 ENFIT
SYRINGES



GTIN: 0117856114131
S/N: XXXXXXXXXXXX
Exp: 09/11/24
Lot: XXXXXXXXXXXX



Packaged by:

Distributed by: Atlantic Biologicals Corp.
Miami, FL 33179

Rev.08/21

Call to Reorder:



17856114101

INFANTS' GAS RELIEF
(SIMETHICONE)
ORAL SUSPENSION, USP
DELIVERS 20mg/0.3mL
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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17856-1141(NDC:71399-0041)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
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			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17856-1141-1	120 in 1 BOX, UNIT-DOSE	09/12/2024	
1	NDC:17856-1141-6	0.3 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:17856-1141-2	120 in 1 BOX, UNIT-DOSE	09/12/2024	
2	NDC:17856-1141-7	0.3 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
3	NDC:17856-1141-3	120 in 1 BOX, UNIT-DOSE	09/12/2024	
3	NDC:17856-1141-8	0.6 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
4	NDC:17856-1141-4	120 in 1 BOX, UNIT-DOSE	09/12/2024	
4	NDC:17856-1141-9	0.6 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 - ATLANTIC BIOLOGICALS CORP (047437707)

Establishment

Name	Address	ID/FEI	Business Operations
UNIT DOSE SOLUTIONS		360804194	repack(17856-1141)

Revised: 9/2024

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