

INFANTS- simethicone suspension/ drops
ATLANTIC BIOLOGICALS CORP.

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

Age (yr)	Weight (lb)	Dose (mL)
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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

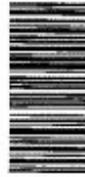


See package insert for indications and dosage schedule

See package insert for indications and dosage schedule

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

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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

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Morrisville, NC 27560

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Miami FL 33179

Rev. 09/19

Call to Reorder: 800.509.7592

Rev. 09/19

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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

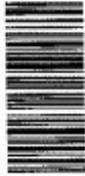


See package insert for indications and dosage schedule

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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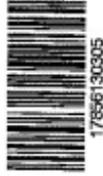
Rev. 09/19

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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



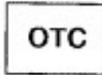
Store at room temperature. Do not freeze.
KEEP OUT OF THE REACH OF CHILDREN

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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17856-1303(NDC:0536-1303)
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	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

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 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:17856-1303-2	120 in 1 BOX, UNIT-DOSE	06/30/2021	
2		0.3 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
3	NDC:17856-1303-3	120 in 1 BOX, UNIT-DOSE	06/30/2021	
3		0.6 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
4	NDC:17856-1303-4	120 in 1 BOX, UNIT-DOSE	06/30/2021	
4		0.6 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
5	NDC:17856-1303-5	60 in 1 BOX, UNIT-DOSE	06/30/2021	
5		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	M002	09/01/2020	

Establishment

Name	Address	ID/FEI	Business Operations
Unit Dose Solutions		360804194	repack(17856-1303)

Revised: 4/2025

ATLANTIC BIOLOGICALS CORP.