

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.

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

Age (years)	Weight (lbs)	Dose
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

17856-5894-02

**Infants' Gas Relief Drops
(Simethicone) Oral
Suspension 40mg/0.6mL**



See package insert for indications and dosage schedule

Store at room temperature. Do not freeze.
AntiGas/Dye Free
KEEP OUT OF THE REACH OF CHILDREN



17856589402

17856-5894-02

Dosage: 40mg/0.6mL

Infants' Gas Relief Drops

**Qty: 120 ENFIT
SYRINGES**



GTIN: 00117856589426

S/N: 01061001

Exp: 12/09/20

Lot: 010610

OTC

Packaged by: Unit Dose Solutions
Morrisville, NC 27560

Distributed by: AtlanticBiologicals Corp.
Miami FL 33179

Rev. 09/19

Call to Reorder: 800.509.7592

17856-5894-06
INFANTS' GAS RELIEF
DROPS (SIMETHICONE)
ORAL SUSPENSION (20
mg/0.3 ml) Delivers 40
mg/0.6ml



See package insert for indications and dosage schedule

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



17856-5894-06

Dosage: 0.6 mL

INFANTS' GAS RELIEF

Qty: 120 Syringes



GTIN: 00117856589464

S/N: 00855801

Exp: 05/12/20

Lot: 008558

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

INFANTS GAS RELIEF

simethicone suspension/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17856-5894(NDC:0904-5894)
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)	
MALTITOL (UNII: D65DG142WK)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
ANHYDROUS TRISODIUM CITRATE (UNII: RS7A450LGA)	
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:17856-5894-4	60 in 1 CASE	06/30/2021	
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	06/30/2021
3	NDC:17856-5894-3	.3 mL in 1 SYRINGE; Type 0: Not a Combination Product	06/30/2021	
4	NDC:17856-5894-7	120 in 1 BOX, UNIT-DOSE	06/30/2021	
4		.3 mL in 1 SYRINGE; Type 0: Not a Combination Product		
5	NDC:17856-5894-2	120 in 1 BOX, UNIT-DOSE	06/30/2021	
5		0.6 mL in 1 SYRINGE; Type 0: Not a Combination Product		
6	NDC:17856-5894-6	120 in 1 BOX, UNIT-DOSE	06/30/2021	
6		0.6 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: 6/2021

Atlantic Biologicals Corps