

**INFANTS GAS RELIEF- simethicone solution/ drops**  
**Topco Associates, LLC**

*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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**Topco Infants Gas Relief Drops**

**ACTIVE INGREDIENT (in each 0.3 mL)**

Simethicone 20 mg

**PURPOSE**

Antigas

**USE(S)**

relieves the symptoms of gas frequently caused by air swallowing or certain formulas or foods

**WARNINGS**

**When using this product** do not exceed 12 doses per day

**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
- fill enclosed dropper to recommended dosage level
- dispense liquid slowly into baby's mouth, toward the inner cheek
- may mix with 1 oz. of cool water, infant formula or other suitable liquids
- clean dropper after each use and close the bottle to maintain child resistance

age (yr)	weight (lb)	dose
infants under 2	under 24	0.3 mL
children over 2	over 24	0.6 mL

## **OTHER INFORMATION**

store at room temperature

## **INACTIVE INGREDIENTS SECTION**

benzoic acid, flavor, magnesium aluminum silicate, purified water, simethicone emulsion, sorbitol, xanthan gum

## **PRINCIPAL DISPLAY PANEL**

Topcare health

COMPARE TO MYLICON<sup>®</sup> NON-STAINING INFANTS' DROPS ACTIVE INGREDIENT\*

NDC 36800-119-09

NON-STAINING

DYE-FREE

infants'

**Gas Relief**

**Drops**

SIMETHICONE 20 mg

ANTI-GAS

- **Gently Breaks Down Baby's Gas Bubbles**
- **Safe Enough to Use at Every Feeding\*\***

\*\*use as directed

1 FL OZ (30 mL)



## INFANTS GAS RELIEF

simethicone solution/ drops

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-119
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength

<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>MAGNESIUM ALUMINUM SILICATE</b> (UNII: 6M3P64V0NC)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<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>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-119-09	1 in 1 CARTON	03/01/2013	
1		30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part332	03/01/2013	

**Labeler** - Topco Associates, LLC (006935977)

### Establishment

Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	MANUFACTURE(36800-119)

Revised: 5/2021

Topco Associates, LLC