

**TOPCARE GAS RELIEF- simethicone emulsion**  
**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.*

-----

**Topco Associates LLC. Gas Relief Drops Drug Facts**

**Active ingredient (in each 0.3 mL)**

Simethicone 20 mg

**Purpose**

Antigas

**Uses**

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 (1-800-222-1222).

**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. If you pass the prescribed level, simply push syringe back until you have reached the desired 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)
infants under 2	under 24	0.3
children over 2	over 24	0.6

## **Other information**

- **do not use if printed bottle wrap is broken or missing**
- store at 20-25°C (68-77°F)
- do not freeze

## **Inactive ingredients**

anhydrous citric acid, flavor, hypromellose, maltitol solution, purified water, simethicone emulsion, sodium benzoate, sodium citrate, xanthan gum

## **Questions or comments?**

**1-888-423-0139**

## **Principal Display Panel**

COMPARE TO INFANTS' MYLICON<sup>®</sup> ACTIVE INGREDIENT

NON-STAINING

DYE-FREE DROPS

infants'

Gas Relief Drops

SIMETHICONE 20 mg

ANTI-GAS

OUR PHARMACISTS RECOMMEND

Gently Breaks Down Baby's Gas Bubbles

Safe Enough to Use at Every Feeding\*\*

\*\*use as directed

1 FL OZ (30 mL)



## TOPCARE GAS RELIEF

simethicone emulsion

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-882
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
XANTHAN GUM (UNII: TTV12P4NEE)	

### Product Characteristics

<b>Color</b>	WHITE (white to off white, opaque)	<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:36800-882-10	1 in 1 CARTON	11/20/2003	
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	11/20/2003	

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

Revised: 6/2019

Topco Associates LLC