

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® 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
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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				
Color	WHITE (white to off white, opaque)		Score	
Shape			Size	
Flavor			Imprint Code	
Contains				
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)

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Topco Associates LLC