INFANTS GAS RELIEF DYE FREE- simethicone antigas emulsion THE KROGER CO.

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.

Kroger INFANTSs GAS RELIEF Dye free 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.
- 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 or syringe to recommended dosage level and dispense liquid slowly into baby's mouth, toward the inner cheek. **Do not use other syringe, dropper, spoon or dosing device when giving this medicine to your child.**
- dosage can also be mixed with 1 oz. cool water, infant formula or other suitable liquids
- clean dropper well after each use-recap bottle with original cap
- mL = milliliter

Age (yr)	Weight (lb)	Dose (mL)
infants under 2	under 24	0.3

abilduae 2009 200 200 200 200 200 200 200 200 20			
children över 2 över 24 0.6	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, microcrystalline cellulose, natural flavors, polysorbate 60, potassium sorbate, purified water, sodium benzoate, sorbitan monostearate, sorbitol, xanthan gum

Comments or Questions?

855-200-BABY

www.ComfortsForBaby.com

Principal Display Panel

NDC# 30142-171-01

Dye Free Drops

INFANTS' GAS RELIEF

*compare to the active ingredient of INFANTS' MYLICON® DROPS

*see the side panel

Dye Free Drops

INFANTS' GAS RELIEF

SIMETHICONE-ANTIGAS

- Non-Staining formula
- Gently Breaks Down Baby's Gas Bubbles
- No alcohol
- No Artificial Colors or Flavor

1 Fl. OZ (30ml)

100 DOSES

IMPORTANT: Keep this carton for future reference on full labeling

DISTRIBUTED BY THE KROGER CO.

CINCINNATI, OHIO 45202

*THIS PRODUCT IS NOT MANUFACTURED OR DISTRIBUTED BY INFIRST HEALTHCARE INC., THE DISTRIBUTOR OF INFANTS' MYLICON® DROPS. INFIRST HEALTHCARE INC. IS NOT AFFILIATED WITH THE KROGER CO. OR THIS PRODUCT.



INFANTS GAS RELIEF DYE FREE simethicone antigas emulsion Product Information Product Type HUMAN OTC DRUG Item Code (Source) Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10)	DIMETHICONE	20 mg in 0.3 mL	

Inactive Ingredients				
Ingredient Name	Strength			
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311)				
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: NVZ 410H58X)				
SORBITOL (UNII: 506T60A25R)				
XANTHAN GUM (UNII: TTV12P4NEE)				

Product Characteristics			
Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:30142- 171-01	1 in 1 CARTON	07/16/2019			
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	07/16/2019		

Labeler - THE KROGER CO. (006999528)

Revised: 8/2023 THE KROGER CO.