

LEADER INFANTS GAS RELIEF- dimethicone emulsion
Cardinal Health

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.

Leader Infants Gas Relief 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. 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 the inner cheek
- dosage can also be mixed with 1 oz. cool water, infant formula or other suitable liquids
- clean dropper after each use - replace bottle with original cap

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

Other information

- **do not use in printed seal under cap is torn or missing**
- store at room temperature
- do not freeze
- see bottom panel for lot and expiration date

Inactive ingredients

carboxymethylcellulose sodium, citric acid, microcrystalline cellulose, natural flavors, PEG-40 monostearate, potassium sorbate, purified water, sodium benzoate, sorbitan monostearate, sorbitol.

Principal Display Panel

Compare to Infants' Mylicon Drops active ingredient

Infants' Gas Relief Drops

Anti-gas/Simethicone

Non-Staining

suitable for infant use

no artificial colors

no saccharin

alcohol free

1 FL. OZ (30ml)



LEADER INFANTS GAS RELIEF

simethicone emulsion

Product Information

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:37205-119
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (DIMETHICONE)	DIMETHICONE	20 mg in 0.3 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE SODIUM	
ANHYDROUS CITRIC ACID	
CELLULOSE, MICROCRYSTALLINE	
PEG-40 STEARATE	
POTASSIUM SORBATE	
WATER	
SODIUM BENZOATE	
SORBITAN MONOSTEARATE	
SORBITOL	

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:37205-119-10	1 in 1 CARTON		
1		30 mL in 1 BOTTLE, DROPPER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part332	03/08/2010	

Labeler - Cardinal Health (097537435)