INFANTS GAS RELIEF DROPS- simethicone emulsion DOLGENCORP INC

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.

Infants' Gas Relief Drops Simethicone/Antigas 1 FL.OZ. (30 mL)

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 sign or symptoms

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 any other syringe, dropper, spoon or dosing device when giving this medicine to your child.
- remove cap and insert syringe into the prescribed level.
- 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 chick).
- 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

Age (yr)	Weight (lb)	Dose(mL)
infants under 2	under 24	0.3
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, natural flavors, microcrystalline cellulose, polysorbate 60, potassium sorbate, purified water, sodium benzoate, sorbitan monostearate, sorbitol, xanthan gum.

Questions?

1-866-467-2748

Principal Display Panel

NDC 55910-790-01

Compare to active ingredient in infant's Mylicon® Gas Relief

Infants'

Gas Relief

Simethicone Drops / Anti-gas

- Dye- free
- Non-staining formula

Fast, effective relief of infants' gas symptoms

1 FL. OZ. (30 mL)

100 doses

DISTRIBUTED BY: OLD EAST MAIN CO.

100 MISSION RIDGE

GOODLETTSVILLE, TN 37072

100% SATISFACTION GUARANTEED!

(888) 309-9030

*This product is not manufactured or distributed by Infirst Healthcare Inc., the distributor of Infants' Mylicon[®] Gas Relief.

IMPORTANT: Keep this carton for future reference on full labeling



INFANTS GAS RELIEF DROPS

simethicone emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-790
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: NVZ4I0H58X)		
SORBITOL (UNII: 506T60A25R)		
XANTHAN GUM (UNII: TTV12P4NEE)		

ı	Packaging			
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date
:	NDC:55910-790- 01	1 in 1 CARTON	01/14/2020	
	L	30 mL in 1 BOTTLE; 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	01/14/2020	

Labeler - DOLGENCORP INC (068331990)

Revised: 7/2022 DOLGENCORP INC