

MYLICON INFANTS GAS RELIEF ORIGINAL- simethicone emulsion
Infirst Healthcare

Infant's Mylicon Gas Relief Original

Drug Facts

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.
- 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 (toward 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

- **tamper evident: do not use if printed seal under cap is broken or missing**
- store between 20-25°C (68-77°F)
- do not freeze
- see bottom panel for lot number and expiration date

Inactive ingredients

carboxymethylcellulose sodium, citric acid, D&C Red 22, D&C Red 28, microcrystalline cellulose, natural flavors, polysorbate 60, potassium sorbate, purified water, sodium benzoate, sorbitan monostearate, sorbitol, xanthan gum

Questions or comments?

Call 1-855-848-3284 toll free (English and Spanish)

Principal Display Panel

Infants' Mylicon®

Simethicone-Antigas

Gas Relief

Gently breaks down baby's gas bubbles

Original Drops

Non-staining

Safe enough to use at every feeding and up to 12 times per day*

#1 Brand

Recommended by Pediatricians

1 Fl. OZ (30ml)

100 Doses

Visit us at mylicon.com

No Alcohol

No Artificial Flavors

No Saccharin

Gluten Free

Safe enough to use at every feeding and up to 12 times per day*

Safe enough for even the newest of newborns*

*use as directed

Mylicon is a registered trademark of McNeil Consumer Pharmaceuticals Co.

Important: Keep this carton for future reference on full labeling

Manufactured for

infirst Healthcare Inc.

Westport, CT 06880

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Package Label for 30 mL



#1 Brand Recommended by Pediatricians

Drug Facts

Active ingredient (in each 0.3 mL) Purpose
 Simethicone 20 mg.....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.

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#1 Brand Recommended by Pediatricians

Drug Facts (continued)

Other information
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infirst+
 HEALTHCARE
 Manufactured for:
 infirst Healthcare Inc.
 Westport, CT 06880
 ©2015 infirst Healthcare Inc.

NDC 62372-630-30

Infants' MYLICON
 Simethicone-Antigas
Gas Relief

Gently breaks down baby's gas bubbles

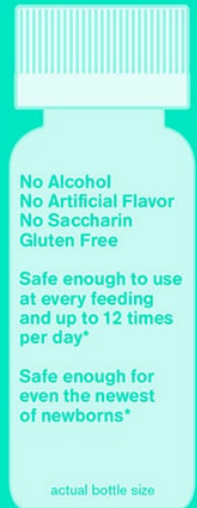


ORIGINAL DROPS
 Safe enough to use at every feeding and up to 12 times per day*



100 Doses 1 FL OZ (30 mL)

Visit us at **mylicon.com**



No Alcohol
 No Artificial Flavor
 No Saccharin
 Gluten Free
 Safe enough to use at every feeding and up to 12 times per day*
 Safe enough for even the newest of newborns*

actual bottle size

*use as directed



765ORG30MYLFC

LOT:

EXP:

Package Label for 15 mL



MYLICON INFANTS GAS RELIEF ORIGINAL

simethicone emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62372-630
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
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C RED NO. 22 (UNII: 1678RKX8RT)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
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)	

Product Characteristics

Color	pink (pink)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62372-630-30	1 in 1 CARTON	03/31/2015	
1		30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:62372-630-15	1 in 1 CARTON	03/31/2015	
2		15 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 Drug	M002	03/31/2015	

Labeler - Infirst Healthcare (079159739)