

INFANTS GAS RELIEF DROPS- simethicone emulsion

Wal-Mart Stores, 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 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 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.

Questions?

1-866-467-2748

Principal Display Panel

*Compare to active ingredient in infant's Mylicon® Drops

Infants'

Gas Relief

Drops

Simethicone 20 mg /Antigas

Dye- free

Non-staining

Formula

No Alcohol

- No Saccharin
- No Artificial Colors
- No Artificial Flavor

1 FL. OZ. (30 mL) 100 doses

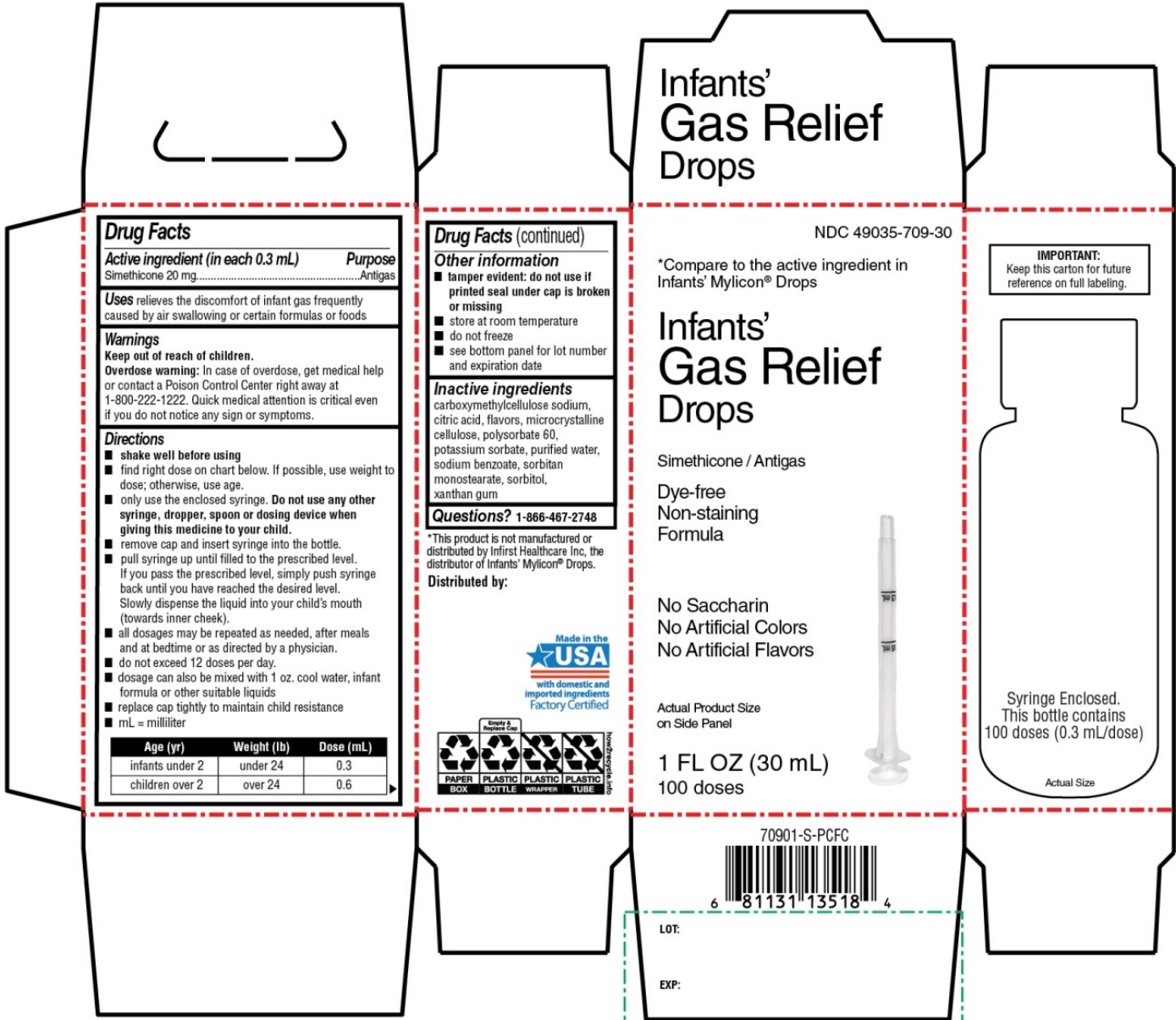
Distributed by:

Made in USA with domestic and imported ingredients.

Factory certified.

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

IMPORTANT: Keep this carton for future reference on full labeling



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 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 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.
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Drug Facts (continued)

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 carboxymethylcellulose sodium, citric acid, flavors, microcrystalline cellulose, polysorbate 60, potassium sorbate, purified water, sodium benzoate, sorbitan monostearate, sorbitol, xanthan gum

Questions? 1-866-467-2748

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Distributed by:

Made in the USA
 with domestic and imported ingredients
 Factory Certified

Recycling logo: PAPER BOX, PLASTIC BOTTLE, PLASTIC WRAPPER, PLASTIC TUBE

Infants' Gas Relief Drops

NDC 49035-709-30

*Compare to the active ingredient in Infants' Mylicon® Drops

Infants' Gas Relief Drops

Simethicone / Antigas

Dye-free
 Non-staining
 Formula

No Saccharin
 No Artificial Colors
 No Artificial Flavors

Actual Product Size on Side Panel

1 FL OZ (30 mL)
 100 doses

70901-S-PCFC

6 81131 13518 4

LOT:
 EXP:

IMPORTANT:
 Keep this carton for future reference on full labeling.

Syringe Enclosed.
 This bottle contains 100 doses (0.3 mL/dose)

Actual Size

Infants Gas Relief Drops



INFANTS GAS RELIEF DROPS

simethicone emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49035-709
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)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0K00R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
SORBITOL (UNII: 506T60A25R)	
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:49035-709-01	1 in 1 CARTON	10/16/2017	
1		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:49035-709-30	1 in 1 CARTON	10/22/2019	
2		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	10/16/2017	

Labeler - Wal-Mart Stores, Inc., (051957769)

Revised: 11/2019

Wal-Mart Stores, Inc.,