

CARDINAL HEALTH INFANTS GAS RELIEF- simethicone suspension/ drops

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.

Cardinal Infants' Gas Relief Simethicone 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.
- 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, simply push syringe back until you have reached the described 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, flavor, microcrystalline cellulose, polysorbate 60, potassium sorbate, purified water, sodium benzoate, sorbitan monostearate, sorbitol, xanthan gum

Questions or comments?

1-866-467-2748

Principal Display Panel

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

NDC 70000-0051-1

Infants'

Gas Relief Drops

Simethicone/Antigas

Dye-free

Non-staining formula

- No Alcohol/No Saccharin
- No Artificial Color
- No Artificial Flavor

1 FL OZ (30 mL) 100 DOSES

Distributed by:

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

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



CARDINAL HEALTH INFANTS GAS RELIEF

simethicone suspension/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0051
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 (UNII: K679OBS311)	
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)	

Product Characteristics

Color	PINK	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0051-1	1 in 1 CARTON	09/02/2020	
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	09/02/2020	

Labeler - CARDINAL HEALTH (063997360)

Revised: 10/2023

CARDINAL HEALTH