# INFANTS GAS RELIEF NON-STAINING FORMULA- dimethicone liquid Walgreens

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.

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Infant's Gas Relief Non-Staining Formula

**Drug Facts** 

### Active ingredient (in each 0.3 mL)

Simethicone 20 mg

### **Purpose**

Anti-gas

### 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.

(1-800-222-1222)

### **Directions**

- shake well before using
- all doses may be repeated as needed, after meals and at bedtime or as directed by a physician. Do not exceed 12 doses per day
- 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 hole at top of bottle and turn upside down. Pull back plunger of syringe until syringe filled slightly over prescribed level. Turn to original position, simply push plunger back until you have reached the prescribe level. Pull syringe out of the bottle and dispense liquid slowly into baby's mouth, toward the inner cheek.
- dosage can be mixed with 1 oz. of cool water, infant formula or other suitable liquids
- for best results, clean syringe after each use and replace 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 if the neck wrap imprinted with "Safety Seal" is broken or missing
- store at room temperature
  - do not freeze

• see bottom panel for lot number and expiration date

### **Inactive ingredients**

Carbomer 934-P, Citric Acid, Hydroxypropyl Methylcellulose, Natural Flavors, Purified Water, Sodium Benzoate, Sodium Citrate, Sucralose

### Questions or comments?

1-800-Walgreens (1-800-925-4733)

DISTRIBUTED BY: WALGREEN CO. 200 WILMOT ROAD DEERFIELD, IL 60015

### PRINCIPAL DISPLAY PANEL - 30 mL Bottle Carton

Well at

Walgreens

WALGREENS PHARMACIST RECOMMENDED<sup>‡</sup>

Infants'

**Gas Relief** 

Simethicone 20 mg/Dose

**Anti-Gas** 

- Nonstaining formula
- No alcohol
- No saccharin
- No artificial flavor
- New dosing syringe design

### **100 DOSES**

Compare to Infants' Mylicon® Drops active ingredient‡‡

1 FL OZ (30 mL)



Infants'
Gas Relief

Simethicone 20 mg/Dose Anti-Gas



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\*Walgreens Pharmacist Survey Study, November 2012.

This product is not manufactured or distributed by McNeil Consumer Pharmaceuticals Co., the distributor of Infants' Mylicon\* Drops.

DISTRIBUTED BY: WALGREEN CO. 200 WILMOT ROAD DEERFIELD, IL 60015

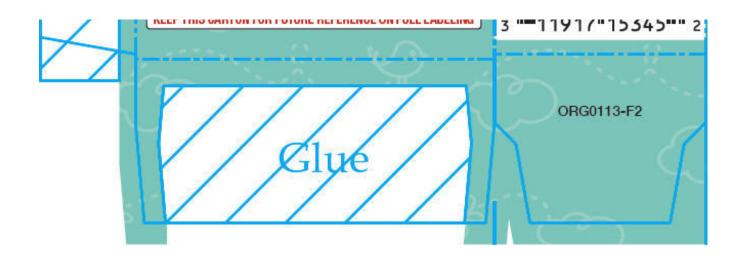
SATISFACTION GUARANTEED

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ITEM 230831



KEED THIS CARTON FOR FITTIRE REFERENCE ON FILL LARFLING



### INFANTS GAS RELIEF NON-STAINING FORMULA

dimethicone liquid

### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0363-5345

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		
Sodium Benzoate (UNII: OJ245FE5EU)			
Citric Acid Monohydrate (UNII: 2968 PHW8 QP)			
Hypromelloses (UNII: 3NXW29V3WO)			
Carbomer Homopolymer Type B (Allyl Sucrose Crosslinked) (UNII: Z135WT9208)			
Sucralose (UNII: 96K6UQ3ZD4)			
Vanillin (UNII: CHI530446X)			
Sodium Citrate (UNII: 1Q73Q2JULR)			
Water (UNII: 059QF0KO0R)			

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	VANILLA, STRAWBERRY	Imprint Code	
Contains			

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1 NDC:0363-5345-01	1 in 1 CARTON		
1	30 mL in 1 BOTTLE, DROPPER		
Marketing Inform	nation		
Marketing Category	Application Number or Monograph Cita	tion Marketing Start D	ate Marketing End Date
OTC MONOGRAPH FINAL	part332	0 4/15/20 13	

# Labeler - Walgreens (008965063)

# Registrant - davAgen Pharmaceutical, LLC (967545935)

Establishment			
Name	Address	ID/FEI	Business Operations
davAgen Pharmaceutical, LLC		967545935	MANUFACTURE(0363-5345), PACK(0363-5345), LABEL(0363-5345), ANALYSIS(0363-5345)

Revised: 12/2013 Walgreens