

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.

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[‡]

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)

Well at
Walgreens

Infants'
Gas Relief

Simethicone 20 mg/Dose
Anti-Gas



Well at
Walgreens

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LOT

NO COATING

EXP

Glue

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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

Walgreens
100%
SATISFACTION
GUARANTEED

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ITEM 230831



KEEP THIS CARTON FOR FUTURE REFERENCE ON FILL I LABELING



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: 2968PHW8QP)	
Hypromelloses (UNII: 3NXW29V3WO)	
Carbomer Homopolymer Type B (Allyl Sucrose Crosslinked) (UNII: Z135WT9208)	
Sucralose (UNII: 96K6UQ3ZD4)	
Vanillin (UNII: CH530446X)	
Sodium Citrate (UNII: 1Q73Q2JULR)	
Water (UNII: 059QF0K00R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	VANILLA, STRAWBERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:0363-5345-01	1 in 1 CARTON		
1		30 mL in 1 BOTTLE, DROPPER		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part332	04/15/2013	

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

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