

INFANTS RELIEF NON-STAINING FORMULA- dimethicone 410 liquid
CVS

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.

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
- fill enclosed dropper to recommended dosage level 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 dropper 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 printed foil seal under cap is torn 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

Distributed by: CVS/pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

PRINCIPAL DISPLAY PANEL - 15 mL Bottle Carton

CVS[®]

pharmacy

Compare to the

active ingredient in

Infants' MYLICON[®] Drops*

Infants'

GAS

RELIEF

NON-STAINING FORMULA

SIMETHICONE/ANTIGAS

- ***No alcohol***
- ***No saccharin***
- ***No artificial
flavor***

50 Doses

0.5 FL OZ (15 mL)



INFANTS RELIEF NON-STAINING FORMULA

dimethicone 410 liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-102
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Dimethicone 410 (UNII: TYU5GP6XGE) (Dimethicone 410 - UNII:TYU5GP6XGE)	Dimethicone 410	20 mg in 0.3 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium Benzoate (UNII: OJ245FE5EU)	
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
Hypromelloses (UNII: 3NXW29V3WO)	
Sucralose (UNII: 96K6UQ3ZD4)	

Vanillin (UNII: CH530446X)	
Sodium Citrate (UNII: 1Q73Q2JULR)	
Water (UNII: 059QF0KO0R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	VANILLA, STRAWBERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-102-05	1 in 1 CARTON		
1		15 mL in 1 BOTTLE, DROPPER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part332	02/03/2012	

Labeler - CVS (062312574)

Registrant - davAgen Pharmaceutical, LLC (967545935)

Establishment

Name	Address	ID/FEI	Business Operations
davAgen Pharmaceutical, LLC		967545935	MANUFACTURE, PACK, LABEL, ANALYSIS

Revised: 6/2012

CVS