

INFANTS GAS DROPS- simethicone suspension/ drops
Rij Pharmaceutical Corporation

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.

Drug Facts

Active ingredients (in each 0.3mL)

Simethicone 20 mg

Purpose

Antigas

Uses

Relieves the discomfort of 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 dosages 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 also 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 (yrs)	Weight (lbs)	Dose (ml)
Infants under 2	Under 24	0.3 mL
Children over 2	Over 24	0.6 mL

Other Information

TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF PRINTED INNER CAP SEAL IS BROKEN OR MISSING

- Store at room temperature 15° - 30°C (59 - 86°F)
- protect from freezing
- each 0.3 mL contains: sodium 1 mg

Inactive ingredients

carbopol - 934-P, citric acid, FD&C red #3, flavor, hypromellose, sodium benzoate, sodium citrate,

sodium hypochlorite, sodium saccharin, water

Principal Display Panel



NDC 53807-523-30
Compare To
Mylicon Drops[†]

**Infants'
GAS DROPS**

Simethicone / Antiflatulent
Gas Symptom
Relief for Infants
Cherry Flavored



1 fl. oz.
(30 mL)



Important: Save box for complete directions and warnings

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[†] This product is not manufactured or distributed by Johnson & Johnson, owner of the registered trademark Mylicon Drops[®]. All Preferred Plus Pharmacy products are satisfaction guaranteed or your money back from retailer where purchased

Dist. By: Kinray Inc. Whitestone, NY 11357 REV. 10/09

INFANTS GAS DROPS			
simethicone suspension/ drops			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53807-523
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 (UNII: 9NEZ333N27)			
CARBOMER HOMO POLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)			
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)			
HYPROMELLOSES (UNII: 3NXW29V3WO)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
SODIUM CITRATE (UNII: 1Q73Q2JULR)			
SODIUM HYPOCHLORITE (UNII: DY38VHM5OD)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
WATER (UNII: 059QF0K00R)			

Product Characteristics

Color	PINK	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53807-523-30	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/16/1996	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part332	03/16/1996	

Labeler - Rij Pharmaceutical Corporation (144679156)**Establishment**

Name	Address	ID/FEI	Business Operations
Rij Pharmaceutical Corporation		144679156	manufacture(53807-523)

Revised: 4/2018

Rij Pharmaceutical Corporation