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

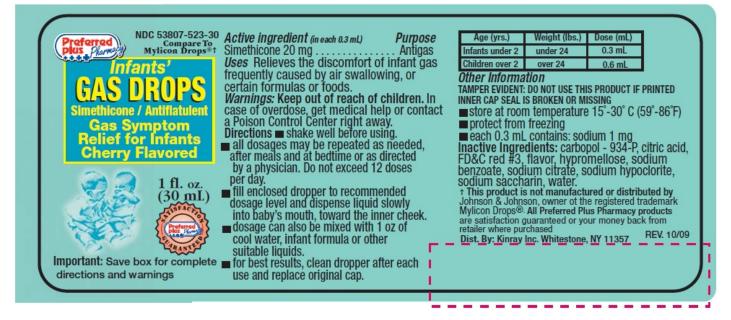
TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF PRINTED INNER CAP SEAL IS BROKEN OR MISSING

- 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,

Principal Display Panel



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 Moi	ety					
Ingredient Name		Basis of Strengt	h S	trength		
Dimethicone (UNII: 92RU3N3Y1O) (Dir	nethicone - UNII:92RU3N3Y1O)		Dimethicone	20 mg	in 0.3 mL	
Inactive Ingredients						
	Ingredient Name				Strength	
SODIUM (UNII: 9NEZ333N27)						
CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)						
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)						
FD&C RED NO.3 (UNII: PN2ZH5LOQY						
HYPROMELLOSES (UNII: 3NXW29V3						
SODIUM BENZOATE (UNII: OJ245FE5						
SODIUM CITRATE (UNII: 1Q73Q2JUL						
SODIUM HYPOCHLORITE (UNII: DY3	,					
SACCHARIN SO DIUM (UNII: SB8ZUX-	40 I Y)					
WATER (UNII: 059QF0KO0R)						

Product Characteristics						
Color		PINK	Score			
Shape			Size			
Flavor		CHERRY	Imprint Code			
Contains						
Packaging						
# Item Code		Package Description		Marketing Start Date	Marketing l	End Date
1 NDC:53807-523-30 3	0 mL in 1 BO	nL in 1 BOTTLE; Type 0: Not a Combination Product		03/16/1996		
Marketing Information						
Marketing Category	Appli	cation Number or Monogra	ph Citation	Marketing Start Date	Marketing I	End Date
OTC MONOGRAPH FINA	L 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