

INFANTS GAS RELIEF DROPS- simethicone emulsion

Select Brand

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.

Select Brand Infant's Gas Relief Drops

Active ingredient (in each 0.3 mL)

simethicone 20 mg

Purpose

Antigas

Uses

relieves the symptoms of gas frequently caused by air swallowing or certain formulas or foods

Warnings

When using this product

do not exceed 12 doses per day

Keep out of reach of children. In case of overdose get medical help or contact a poison control center immediately.

Directions

- shake well before using
- all dosages may be repeated as needed, after meals and at bedtime
- fill enclosed dropper to recommend dosage level
- dispense liquid slowly into baby's mouth, toward the inner cheek
- may mix with 1 oz. of cool water, infant formula or other suitable liquids
- clean dropper after each use and close the bottle to maintain child resistance

age (yr)	weight (lb)	dose
infants under 2	under 24	0.3 mL
children over 2	over 24	0.6 mL

Other information

store at room temperature

Inactive ingredients

benzoic acid, flavor, magnesium aluminum silicate, purified water, simethicone emulsion, sorbitol, xanthan gum

Principal Display Panel

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Compare to the active ingredient in Infants Mylicon[®] Drops

Infant's Gas Relief Drops

Simethicone

Anti-Gas

Non-staining

Excess Gas relief

Alcohol Free

Saccharin Free

No Artificial Flaovr

1 fl oz (30 mL)



INFANTS GAS RELIEF DROPS

simethicone emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:15127-042
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
SORBITOL (UNII: 506T60A25R)	

XANTHAN GUM (UNII: TTV12P4NEE)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:15127-042-17	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	02/02/2013	

Labeler - Select Brand (043562370)

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