# INFANTS GAS RELIEF DROPS- simethicone suspension/ drops RELIABLE 1 LABORATORIES

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### **REL infant drops**

## Active ingredient (in each 0.3 mL)

Simethicone 20 mg

## **Purpose**

**Antigas** 

#### Use

relieves the symptoms referred to as gas

## 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
- only use the enclosed dropper
- 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
- clean dropper well after each use and replace original cap on bottle

Age (years)	Weight (lbs)	Dose
infants (under 2)	under 24	0.3 mL
children (2 and over)	24 and over	0.6 mL

#### Other information

- TAMPER-EVIDENT: Do not use if foil seal under the cap is broken or missing.
- store between 20°-25°C (68°-77°F)

- do not freeze
- see bottom panel for lot number and expiration date

## **Inactive ingredients**

carboxymethylcellulose sodium, citric acid, flavor, maltitol, microcrystalline cellulose, purified water, sodium benzoate, sodium citrate, xanthan gum.

#### Questions or comments?

call **516-341-0666** 8:30 am - 4:30 pm ET, Monday - Friday

## package Label



### INFANTS GAS RELIEF DROPS

simethicone suspension/ drops

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69618-059	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10)	DIMETHICONE	20 mg in 0.3 mL	

Inactive Ingredients				
Ingredient Name	Strength			
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K6790BS311)				
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
MALTITOL (UNII: D65DG142WK)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
WATER (UNII: 059QF0KO0R)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SODIUM CITRATE (UNII: 1Q73Q2JULR)				
XANTHAN GUM (UNII: TTV12P4NEE)				

Product Characteristics				
Color	white (off-white)	Score		
Shape		Size		
Flavor	CHERRY	Imprint Code		
Contains				

F	Packaging				
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:69618- 059-51	1 in 1 CARTON	02/01/2020		
1		30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M002	02/01/2020	

## Labeler - RELIABLE 1 LABORATORIES (079718111)

## Registrant - GCP Laboratories (965480861)

Establishment				
Name	Address	ID/FEI	Business Operations	
GCP Laboratories		965480861	manufacture(69618-059)	

Revised: 11/2023 RELIABLE 1 LABORATORIES