

**LITTLE REMEDIES GAS RELIEF DROPS- simthicone liquid
Medtech Products Inc.**

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.

Little Remedies Gas Relief Drops

Drug Facts

Active ingredient (in each 0.3 mL)

Simethicone Emulsion USP 66.7 mg/ Simethicone 20 mg

Purpose

Antigas

Uses

Relieves discomfort of infant gas frequently caused by excessive swallowing of air or certain formulas or food.

Warnings

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- shake well before using
- only use enclosed dropper / syringe; fill to prescribed level and dispense liquid slowly into child's mouth, toward inner cheek
- 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
- dosage can also be mixed with 1 fl oz of cool water, infant formula or other suitable liquids
- for best results, clean dropper after each use and replace original cap

If possible, use weight to determine dose; otherwise use age.

mL = milliliter

Age (yrs)	Weight (lbs)	Dose
Newborns & Infants under 2	Under 24	0.3 mL
Children 2 and over	24 and over	0.6 mL

Other information

- do not freeze

- store at room temperature 20°-25°C (68°-77°F)
- see bottle or box for lot number and expiration date

Inactive ingredients

carmellose sodium (and) microcrystalline cellulose, citric acid, natural strawberry flavor, propylene glycol, purified water, sodium benzoate, sucralose, xanthan gum

Questions?

1-800-754-8853

Mon. – Fri. 8:30 am to 5:30 pm EST

LittleRemedies.com

PRINCIPAL DISPLAY PANEL

Little Remedies
Gas Relief Drops
Simethicone / Antigas
0.5 FL OZ (15 mL)



PRINCIPAL DISPLAY PANEL

Little Remedies
 Gas Relief Drops
 Simethicone / Antigas
 1.0 FL OZ (30 mL)



LITTLE REMEDIES GAS RELIEF DROPS

simethicone liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63029-103
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
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63029-103-01	1 in 1 CARTON	06/01/2012	
1		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:63029-103-02	1 in 1 CARTON	01/04/2010	
2		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 FINAL	part332	01/04/2010	

Labeler - Medtech Products Inc. (122715688)

Revised: 12/2017

Medtech Products Inc.