Little Remedies Infant Essentials Kit

GAS RELIEF DROPS Simethicone / Antigas

Drug Facts

Active ingredient (in each 0.3 mL)

Purpose

Simethicone Emulsion USP 66.7 mg/ Simethicone 20 mg . . . . . ……..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.

Directions

■ shake well before using

■ only use enclosed 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 oz. of cool water, infant formula or other suitable liquids

■ for best results, clean syringe after each use and replace original cap

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

mL = milliliters

Age (yrs)	Weight (lbs)	Dose
Newborns & Infants under 2 years	under 24	0.3 mL
Children 2 years 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,citric acid, microcrystalline cellulose, natural strawberry flavor, propylene glycol, purified water, sodium benzoate, sucralose, xanthan gum

GRIPE WATER

Supplement Facts **Serving Size: 5 mL** **Servings per Container: about 12**	
Amount per Serving	**% Daily Value**
Zingiber officinale (Ginger) Root Extract 5 mg	†
Foeniculum vulgare (Fennel) Seed Extract 4mg	†
†Daily Value not established	

Other ingredients

purified water, agave, glycerin, natural ginger flavor, potassium sorbate, citric acid, xanthan gum

Suggested Use	
Age	**Dose**
2 to 4 weeks	2.5 mL
1 to 6 months	5 mL
6 months and older	10 mL
Adults	30 mL

Exhibit 1048
Dr. Berkland

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SHAKE WELL. May be taken directly using the dispenser included. May be given up to six times in a 24 hour period. If necessary to repeat dosage, wait a minimum of 30 minutes. Do not use if safety seal is broken or missing.

Keep out of reach of children.

In some infants, a rare allergic reaction may occur. Do not exceed recommended dosage.

Do not use if

- child has a history of kidney failure or renal problems
- child is allergic to any of the ingredients in this product Always consult your health care provider before giving this or any supplement to an infant.
- Store at room temperature.

SALINE SPRAY + DROPS

Uses

–Helps loosen mucus secretions to aid aspiration and removal from nose and sinuses, allowing for easier breathing. For infants this can be assisted with the use of our specially designed “Soft Tip” Nasal Aspirator.

Warnings

Keep out of reach of children.

▪ **The use of this dispenser by more than one person may spread infection.**

▪ Wipe nozzle clean after each use.

Directions (For nasal use only)

▪ **Infants:** 2 to 6 drops in each nostril as often as needed or as directed by your doctor.

▪**Children:** 2 to 6 sprays or drops into each nostril as often as needed or as directed by a doctor.

Store at 20°-25°C (68°-77°F).

See bottle for lot and expiration date.

Ingredients:

water, sodium chloride, glycerin, sodium benzoate, benzoic acid

PRINCIPAL DISPLAY PANEL

Little Remedies®

Infant Essentials Kit

GAS DROPS

SIMETHICONE /ANTIGAS

1 FL OZ (30 mL)

Syringe Included

SALINE SPRAY + DROPS

0.5 FL OZ (15 mL)

GRIPE WATER

GINGER / FENNEL SUPPLEMENT

2 FL OZ (59 mL)

Syringe Included

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LITTLE REMEDIES INFANT ESSENTIALS

simethicone emulsion, simethicone, zingiber officinale (ginger) root, foeniculum vulgare (fennel) seed kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63029-609

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63029-609-01	1 in 1 CARTON; Type 0: Not a Combination Product	02/15/2019	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	30 mL
Part 2	1 BOTTLE, DROPPER	15 g
Part 3	1 BOTTLE	59 mL

Part 1 of 3

LITTLE REMEDIES RELIEF

simethicone liquid

Product Information

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)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

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CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	WHITE	**Score**	
Shape		**Size**	
Flavor	BERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		30 mL in 1 BOTTLE; 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	02/15/2017	

Part 2 of 3

SALINE

other baby products spray

Product Information

Route of Administration	NASAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	**GLYCERIN** (UNII: PDC6A3C0OX)	
INGR	**SODIUM BENZOATE** (UNII: OJ245FE5EU)	
INGR	**BENZOIC ACID** (UNII: 8SKN0B0MIM)	
INGR	**WATER** (UNII: 059QF0KO0R)	
INGR	**SODIUM CHLORIDE** (UNII: 451W47IQ8X)	

Product Characteristics

Color	WHITE (Beige)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		15 g 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
COSMETIC		02/15/2017	

Part 3 of 3

GRIPE WATER

ginger root / fennel seed liquid

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Product Information

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GINGER (UNII: C5529G5JPQ) (GINGER - UNII:C5529G5JPQ)	GINGER	5 mg in 5 mL
FENNEL (UNII: 557II4LLC3) (FENNEL - UNII:557II4LLC3)	FENNEL	4 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
AGAVE TEQUILANA JUICE (UNII: GVG8G0207O)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	WHITE (clear)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		59 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		02/15/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		02/15/2019	

Labeler - Medtech Products Inc. (122715688)

Revised: 1/2020 Medtech Products Inc.

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