

**LITTLE REMEDIES NEW BABY ESSENTIALS- acetaminophen, simethicone, zinc oxide
Medtech Products Inc.**

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).

Little Remedies New Baby Essentials Kit

FOR FEVERS™

INFANT FEVER + PAIN RELIEVER Acetaminophen

Drug Facts

Active ingredient

(in each 5 mL)

Acetaminophen 160 mg

Purpose

Pain reliever / Fever reducer

Uses

Temporarily:

- reduces fever
- relieves minor aches and pains which may be associated with the common cold, flu, headache, sore throat or toothache.

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if your child takes ▪ more than 5 doses in 24 hours, which is the maximum daily amount ▪ with other drugs containing acetaminophen.

Sore Throat Warning: If sore throat is severe, persists for more than 2 days, or is accompanied or followed by fever, headache, rash, nausea or vomiting, consult a doctor promptly.

Allergy Alert: Acetaminophen may cause severe skin reactions. Symptoms may include: ▪ skin reddening ▪ blisters ▪ rash. If a skin reaction occurs, stop use and seek medical help right away.

Do not use

- with any other products containing acetaminophen (prescription or non-prescription).
- If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if your child is allergic to acetaminophen or any of the inactive ingredients in this product.

Ask a doctor before use if the child has

liver disease.

Ask a doctor or pharmacist before use if the child is

taking the blood thinning drug warfarin.

When using this product

do not exceed recommended dose (see overdose warning)

Stop use and ask a doctor if

- new symptoms occur
- fever gets worse or lasts more than 3 days
- pain gets worse or lasts more than 5 days
- redness or swelling is present. These could be signs of a serious condition.

Keep out of reach of children.

Overdose Warning: Taking more than the recommended dose (overdose) can cause serious liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. **Prompt medical attention is critical even if you do not notice any signs or symptoms.**

Directions

This product does not contain directions or complete warnings for adult use.

- **Shake well before using**
- Find the right dose on the chart on the chart below. If possible, use weight to determine dose; otherwise, use age.
- Only use the enclosed AccuSafe® syringe. **Do not use any other syringe, dropper, spoon or dosing device when giving this medicine to your child.**
- Remove cap, insert syringe to flow restrictor and invert bottle
- Pull back syringe until filled to the prescribed level and slowly dispense the liquid into your child's mouth (towards the inner cheek)
- If needed, repeat dose every 4 hours while symptoms last
- Do not give more than 5 times in any 24-hour period (see overdose warning)
- Do not give more than 5 days unless directed by a doctor
- Replace cap tightly to maintain child resistance

mL = milliliter

Weight (lbs)	Age (yrs)	Dose (mL)
Under 24	under 2	Ask a doctor
24-35	2-3	5 mL

Other information

- Store at 20°-25°C (68°-77°F)
- AccuSafe® Oral dosing device enclosed
- Check expiration date on bottle or box before using.

Inactive ingredients

benzoic acid, carboxymethylcellulose, glycerin, natural grape flavor, microcrystalline cellulose, sucrose, sodium benzoate, water, xanthan gum

FOR DIAPER RASH

BOUDREAUX'S BUTT PASTE ® Diaper Rash Ointment

Drug Facts

<p>Active ingredient Purpose Zinc oxide, 16%.....Skin protectant</p>
<p>Uses</p> <ul style="list-style-type: none"> ▪ Helps treat and prevent diaper rash ▪ Protects chafed skin due to diaper rash and helps seal out wetness
<p>Warnings For external use only When using this product avoid contact with the eyes Stop use and ask a doctor if condition worsens or does not improve after 7 days Keep out of the reach of children to prevent accidental ingestion If swallowed, seek medical help or call Poison Control Center (1-800-222-1222) immediately</p>
<p>Directions</p> <ul style="list-style-type: none"> ▪ Change wet and soiled diaper immediately ▪ Cleanse the diaper area and allow to dry ▪ Apply ointment liberally and as often as necessary with each diaper change and especially when exposed to wet diapers for a prolonged period of time, such as bedtime
<p>Other information</p> <ul style="list-style-type: none"> ▪ Store at room temperature 20°- 27°C (68°- 80°F) ▪ Remove seal from jar before use ▪ Use with infants, children and adults ▪ Will stain clothing and fabric
<p>Inactive ingredients castor oil, mineral oil, paraffin, peruvian balsam, white petrolatum</p>
<p>Questions? 1-855-785-2888 www.buttpaste.com</p>

FOR TUMMYS™

GAS RELIEF DROPS Simethicone / Antigas

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.

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

FOR TUMMYS™

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

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.

FOR NOSES™

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®

New Baby Essentials Kit

INFANT FEVER/PAIN RELIEVER

ACETAMINOPHEN / FEVER/PAIN RELIEVER

2 FL OZ (59 mL)

Syringe Included

GAS DROPS

SIMETHICONE /ANTIGAS

1 FL OZ (30 mL)

Syringe Included

DIAPER RASH OINTMENT

ZINC OXIDE / SKIN PROTECTANT

2 OZ (57 g)

SALINE SPRAY + DROPS

0.5 FL OZ (15 mL)

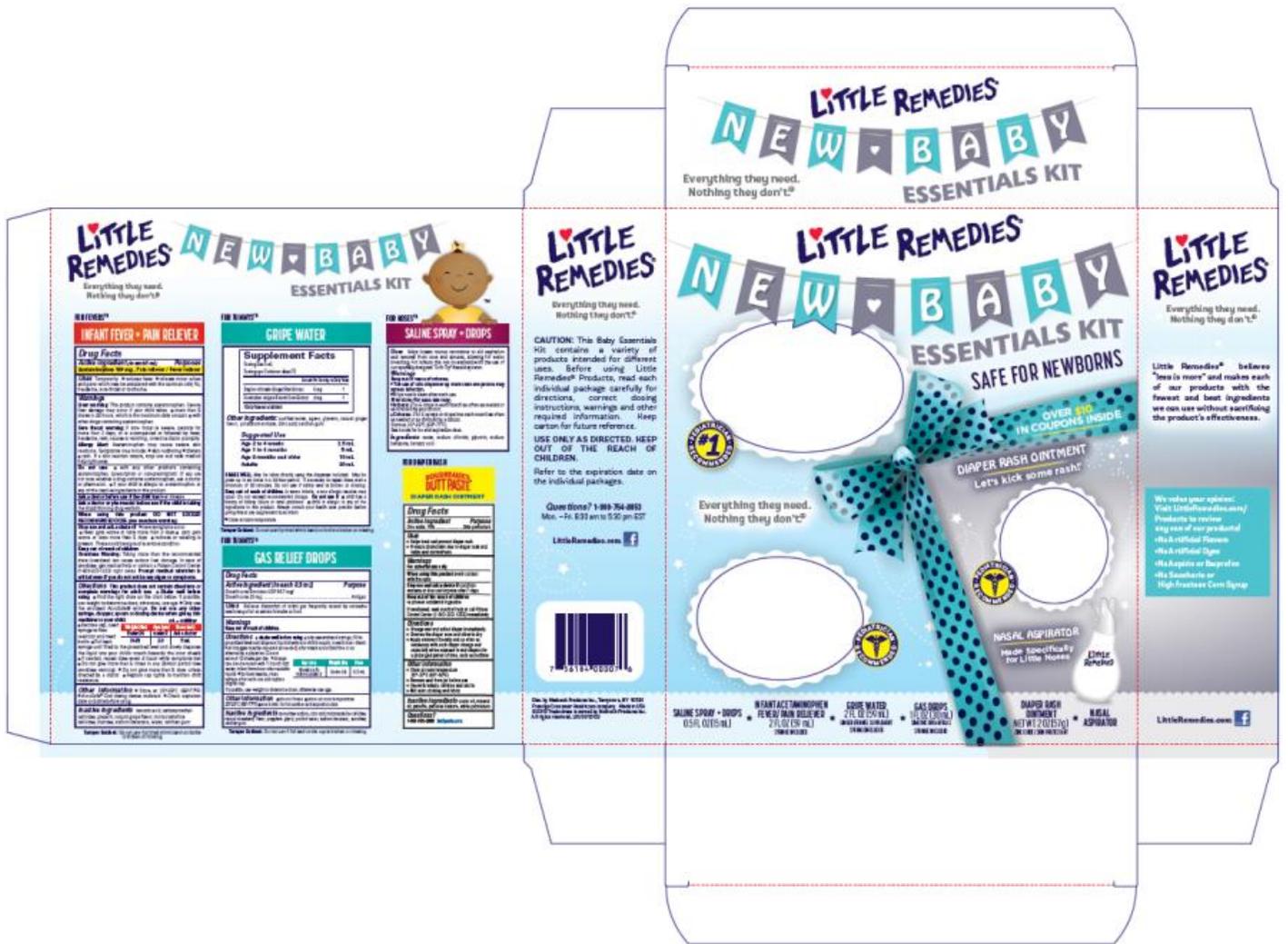
GRIPE WATER

GINGER / FENNEL SUPPLEMENT

2 FL OZ (59 mL)

Syringe Included

Nasal Aspirator



LITTLE REMEDIES NEW BABY ESSENTIALS

acetaminophen, simethicone, zinc oxide kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63029-615
---------------------	----------------	---------------------------	---------------

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63029-615-01	1 in 1 CARTON; Type 0: Not a Combination Product	02/15/2017	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	59 mL
Part 2	1 BOTTLE	30 mL
Part 3	1 TUBE	57 g
Part 4	1 BOTTLE	59 mL
Part 5	1 BOTTLE	15 mL

Part 1 of 5

LITTLE REMEDIES INFANT FEVER AND PAIN RELIEVER

acetaminophen liquid

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	160 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)	
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)	
GLYCERIN (UNII: PDC6A3C0OX)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SUCROSE (UNII: C151H8M554)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
WATER (UNII: 059QF0KO0R)	
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		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
OTC MONOGRAPH NOT FINAL	part343	02/15/2017	

Part 2 of 5

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)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
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 3 of 5

BOUDREAUXS

zinc oxide cream

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	16 g in 113 g

Inactive Ingredients

Ingredient Name	Strength
CASTOR OIL (UNII: D5340Y2I9G)	
MINERAL OIL (UNII: T5L8T28FGP)	
PARAFFIN (UNII: I9O0E3H2ZE)	
BALSAM PERU (UNII: 8P5F881OCY)	
PETROLATUM (UNII: 4T6H12BN9U)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		57 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part347	02/15/2017	

Part 4 of 5

GRIPLE WATER

ginger and fennel liquid

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
WATER (UNII: 059QF0KO0R)	
AGAVE TEQUILANA JUICE (UNII: GVG8G0207O)	
GLYCERIN (UNII: PDC6A3C0OX)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
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	

Part 5 of 5

SALINE

other baby products spray

Product Information

Route of Administration	NASAL
-------------------------	-------

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	

INGR	SODIUM CHLORIDE (UNII: 451W47IQ8X)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
INGR	POTASSIUM PHOSPHATE, UNSPECIFIED FORM (UNII: B7862WZ632)	
INGR	BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
INGR	EDETATE DISODIUM (UNII: 7FLD91C86K)	

Product Characteristics

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

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		02/15/2017	

Labeler - Medtech Products Inc. (122715688)